HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TREMFYA safely and effectively. See full prescribing information for TREMFYA.

TREMFYA® (guselkumab) injection, for subcutaneous use
TREMFYA® PEN (guselkumab) injection, for subcutaneous use
TREMFYA® (guselkumab) injection, for intravenous use

Initial U.S. Approval: 2017

---------- RECENT MAJOR CHANGES ----------

Indications and Usage (1.3)	09/2024
Dosage and Administration (2.1, 2.4, 2.5, 2.6)	09/2024
Warnings and Precautions (5.2, 5.3, 5.4)	09/2024

----------INDICATIONS AND USAGE----------

TREMFYA is an interleukin-23 antagonist indicated for the treatment of adult patients with:

- moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy (1.1)
- active psoriatic arthritis (1.2)
- moderately to severely active ulcerative colitis (1.3)

----------DOSAGE AND ADMINISTRATION----------

- Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to treatment initiation. (2.1)

Recommended Dosage

Plaque Psoriasis

- 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter. (2.2)

Psoriatic Arthritis

- 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter. TREMFYA can be used alone or in combination with a conventional DMARD (e.g., methotrexate). (2.3)

Ulcerative Colitis

- *Induction*: 200 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8. (2.4)
- *Maintenance*: 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. (2.4)

TREMFYA® (guselkumab)

---------- DOSAGE FORMS AND STRENGTHS ----------

Subcutaneous Injection (3)

- Injection: 100 mg/mL in a single-dose One-Press patient-controlled injector.
- Injection: 200 mg/2 mL in a single-dose prefilled pen (TREMFYA PEN).
- Injection: 100 mg/mL in a single-dose prefilled syringe.
- Injection: 200 mg/2 mL in a single-dose prefilled syringe.

Intravenous Infusion (3)

- Injection: 200 mg/20 mL (10 mg/mL) solution in a single-dose vial.

---------- CONTRAINDICATIONS ----------

Serious hypersensitivity reactions to guselkumab or to any of the excipients. (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur. (5.1)
- Infections: TREMFYA may increase the risk of infection. Do not initiate treatment with TREMFYA in patients with clinically important active infection until the infection resolves or is adequately treated. If such an infection develops, discontinue TREMFYA until the infection resolves. (5.2)
- Tuberculosis (TB): Evaluate for TB prior to initiating treatment with TREMFYA. (5.3)
- Immunizations: Avoid use of live vaccines. (5.4)

---------- ADVERSE REACTIONS ----------

Most common adverse reactions associated with TREMFYA are:

- Plaque Psoriasis and Psoriatic Arthritis (≥1%): upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections. (6.1)
- Ulcerative Colitis
- *Induction* (≥2%): respiratory tract infections. (6.1)
- *Maintenance* (≥3%): injection site reactions, arthralgia, and upper respiratory tract infection. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Janssen Biotech, Inc. at 1-800-526-7736 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 09/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Plaque Psoriasis

TREMFYA is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

1.2 Psoriatic Arthritis

TREMFYA is indicated for the treatment of adult patients with active psoriatic arthritis.

1.3 Ulcerative Colitis

TREMFYA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Evaluations and Immunizations Prior to Treatment Initiation

- Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with TREMFYA *[see Warnings and Precautions (5.3)]*.
- Complete all age-appropriate vaccinations according to current immunization guidelines *[see Warnings and Precautions (5.4)]*.

2.2 Recommended Dosage for Plaque Psoriasis

TREMFYA is administered by subcutaneous injection. The recommended dosage is 100 mg at Week 0, Week 4, and every 8 weeks thereafter.

2.3 Recommended Dosage for Psoriatic Arthritis

TREMFYA is administered by subcutaneous injection. The recommended dosage is 100 mg at Week 0, Week 4, and every 8 weeks thereafter.

TREMFYA may be administered alone or in combination with a conventional disease-modifying antirheumatic drug (cDMARD) (e.g., methotrexate).

2.4 Recommended Dosage for Ulcerative Colitis

Induction:

The recommended induction dosage of TREMFYA is 200 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8 *[see Dosage and Administration (2.6)]*.

Maintenance:

The recommended maintenance dosage of TREMFYA/TREMFYA PEN is:

- 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or
- 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter.

Use the lowest effective recommended dosage to maintain therapeutic response.

2.5 Preparation and Administration Instructions for Subcutaneous Injection

- Administer TREMFYA/TREMFYA PEN subcutaneously. Each prefilled syringe, One-Press injector, or Prefilled Pen is for one time use in one patient only. Instruct patients to inject the full amount (1 mL or 2 mL), which provides 100 mg or 200 mg of TREMFYA.
- TREMFYA/TREMFYA PEN is intended for use under the guidance and supervision of a healthcare professional. TREMFYA/TREMFYA PEN may be administered by a healthcare professional, or a patient/caregiver may inject after proper training on correct subcutaneous injection technique.
- Before injection, remove TREMFYA/TREMFYA PEN from the refrigerator and allow to reach room temperature (30 minutes) without removing the needle cap.
- Inject into the front of the thighs, the lower abdomen except for the 2 inches around the navel, or the back of the upper arms (healthcare professional or caregiver only).
- Do not inject TREMFYA/TREMFYA PEN into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis *[see Instructions for Use]*.
- The TREMFYA/TREMFYA PEN *Instructions for Use* contains more detailed patient instructions on the preparation and administration of TREMFYA/TREMFYA PEN *[see Instructions for Use]*.
- If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time.
- Inspect TREMFYA/TREMFYA PEN visually for particulate matter and discoloration prior to administration. TREMFYA/TREMFYA PEN is a clear and colorless to light yellow solution that may contain small translucent particles. Do not use if the liquid contains large particles, is discolored or cloudy. TREMFYA/TREMFYA PEN does not contain preservatives; therefore, discard any unused product remaining in the prefilled syringe, One-Press injector, or Prefilled Pen.

2.6 Preparation and Administration Instructions for Intravenous Infusion (Ulcerative Colitis)

Preparation Instructions:

1. Withdraw and then discard 20 mL of the 0.9% Sodium Chloride Injection from the 250 mL infusion bag which is equal to the volume of TREMFYA to be added.
2. Withdraw 20 mL of TREMFYA from the vial and add it to the 250 mL intravenous infusion bag of 0.9% Sodium Chloride Injection for a final concentration of 0.8 mg/mL. Gently mix the diluted solution. Discard the vial with any remaining solution.
3. Visually inspect the diluted solution for particulate matter and discoloration before infusion. Infuse the diluted solution over a period of at least one hour.
4. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein binding filter (pore size 0.2 micrometer).
5. Do not infuse TREMFYA concomitantly in the same intravenous line with other medicinal products.
6. Dispose any unused medicinal product in accordance with local requirements.

Administration Instructions:

- TREMFYA solution for intravenous infusion must be diluted, prepared, and infused by a healthcare professional using aseptic technique. TREMFYA does not contain preservatives. Each vial is for one time use in one patient only.
- Inspect TREMFYA visually for particulate matter and discoloration prior to administration. TREMFYA is a clear and colorless to light yellow solution that may contain small translucent particles. Do not use if the liquid contains large particles, is discolored, or is cloudy.

Storage of Diluted Solution:

- The diluted infusion solution may be kept at room temperature up to 25°C (77°F) for up to 10 hours. Storage time at room temperature begins once the diluted solution has been prepared. The infusion should be completed within 10 hours after the dilution in the infusion bag.
- Do not freeze.
- Discard any unused portion of the infusion solution.

TREMFYA® (guselkumab)

3 DOSAGE FORMS AND STRENGTHS

TREMFYA/TREMFYA PEN is a clear and colorless to light yellow solution.

Subcutaneous Injection

- Injection: 100 mg/mL in a single-dose One-Press patient-controlled injector.
- Injection: 200 mg/2 mL in a single-dose prefilled pen (TREMFYA PEN).
- Injection: 100 mg/mL in a single-dose prefilled syringe.
- Injection: 200 mg/2 mL in a single-dose prefilled syringe.

Intravenous Infusion

- Injection: 200 mg/20 mL (10 mg/mL) solution in a single-dose vial.

4 CONTRAINDICATIONS

TREMFYA is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with post market use of TREMFYA. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA and initiate appropriate therapy.

5.2 Infections

TREMFYA may increase the risk of infection. In clinical trials in subjects with plaque psoriasis, infections occurred in 23% of subjects in the TREMFYA group versus 21% of subjects in the placebo group through 16 weeks of treatment. Upper respiratory tract infections, gastroenteritis, tinea infections, and herpes simplex infections occurred more frequently in the TREMFYA group than in the placebo group *[see Adverse Reactions (6.1)]*. The rate of serious infections for the TREMFYA group and the placebo group was ≤ 0.2%. A similar risk of infection was seen in placebo-controlled trials in subjects with psoriatic arthritis and ulcerative colitis. Treatment with TREMFYA should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing TREMFYA. Instruct patients to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection or is not responding to standard therapy, monitor the patient closely and discontinue TREMFYA until the infection resolves.

5.3 Pre-treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with TREMFYA. Initiate treatment of latent TB prior to administering TREMFYA. In clinical trials, 105 subjects with plaque psoriasis, 71 subjects with psoriatic arthritis, and 31 subjects with ulcerative colitis with latent TB who were concurrently treated with TREMFYA and appropriate TB prophylaxis did not develop active TB. Monitor patients for signs and symptoms of active TB during and after TREMFYA treatment. Consider anti-TB therapy prior to initiating TREMFYA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Do not administer TREMFYA to patients with active TB infection.

5.4 Immunizations

Avoid use of live vaccines in patients treated with TREMFYA. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy with TREMFYA, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or inactive vaccines.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of labeling:

- Hypersensitivity Reactions *[see Contraindications (4) and Warnings and Precautions (5.1)]*
- Infections *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Plaque Psoriasis

In clinical trials, a total of 1823 subjects with moderate-to-severe plaque psoriasis received TREMFYA. Of these, 1393 subjects were exposed to TREMFYA for at least 6 months and 728 subjects were exposed for at least 1 year.

Data from two placebo- and active-controlled trials (PsO1 and PsO2) in 1441 subjects (mean age 44 years; 70% males; 82% white) were pooled to evaluate the safety of TREMFYA (100 mg administered subcutaneously at Weeks 0 and 4, followed by every 8 weeks).

Weeks 0 to 16:

In the 16-week placebo-controlled period of the pooled clinical trials (PsO1 and PsO2), adverse events occurred in 49% of subjects in the TREMFYA group compared to 47% of subjects in the placebo group and 49% of subjects in the U.S. licensed adalimumab group. Serious adverse events occurred in 1.9% of subjects in the TREMFYA group (6.3 events per 100 subject-years of follow-up) compared to 1.4% of subjects in the placebo group (4.7 events per 100 subject-years of follow-up), and in 2.6% of subjects in U.S. licensed adalimumab group (9.9 events per 100 subject-years of follow-up).

Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the TREMFYA group than in the placebo group during the 16-week placebo-controlled period.

Table 1: Adverse Reactions Occurring in ≥1% of Subjects through Week 16 in PsO1 and PsO2

	TREMFYA[a] 100 mg N=823 n (%)	Adalimumab[b] N=196 n (%)	Placebo N=422 n (%)
Upper respiratory infections[c]	118 (14.3)	21 (10.7)	54 (12.8)
Headache[d]	38 (4.6)	2 (1.0)	14 (3.3)
Injection site reactions[e]	37 (4.5)	15 (7.7)	12 (2.8)
Arthralgia	22 (2.7)	4 (2.0)	9 (2.1)
Diarrhea	13 (1.6)	3 (1.5)	4 (0.9)
Gastroenteritis[f]	11 (1.3)	4 (2.0)	4 (0.9)
Tinea infections[g]	9 (1.1)	0	0
Herpes simplex infections[h]	9 (1.1)	0	2 (0.5)

[a] Subjects receiving 100 mg of TREMFYA at Week 0, Week 4, and every 8 weeks thereafter
[b] U.S. licensed adalimumab
[c] Upper respiratory infections include nasopharyngitis, upper respiratory tract infection (URTI), pharyngitis, and viral URTI.
[d] Headache includes headache and tension headache.
[e] Injection site reactions include injection site erythema, bruising, hematoma, hemorrhage, swelling, edema, pruritus, pain, discoloration, induration, inflammation, and urticaria.
[f] Gastroenteritis includes gastroenteritis and viral gastroenteritis.
[g] Tinea infections include tinea pedis, tinea cruris, tinea infection, and tinea manuum infections.
[h] Herpes simplex infections include oral herpes, herpes simplex, genital herpes, genital herpes simplex, and nasal herpes simplex.

Adverse reactions that occurred in < 1% but > 0.1% of subjects in the TREMFYA group and at a higher rate than in the placebo group through Week 16 in PsO1 and PsO2 were migraine, candida infections, and urticaria.

Specific Adverse Reactions

Infections

Infections occurred in 23% of subjects in the TREMFYA group compared to 21% of subjects in the placebo group.

The most common (≥ 1%) infections were upper respiratory infections, gastroenteritis, tinea infections, and herpes simplex infections; all cases were mild to moderate in severity and did not lead to discontinuation of TREMFYA.

Elevated Liver Enzymes

Elevated liver enzymes were reported more frequently in the TREMFYA group (2.6%) than in the placebo group (1.9%). Of the 21 subjects who were reported to have elevated liver enzymes in the TREMFYA group, all events except one were mild to moderate in severity and none of the events led to discontinuation of TREMFYA.

Safety through Week 48

Through Week 48, no new adverse reactions were identified with TREMFYA use and the frequency of the adverse reactions was similar to the safety profile observed during the first 16 weeks of treatment.

Psoriatic Arthritis

TREMFYA was studied in two placebo-controlled trials in subjects with psoriatic arthritis (748 subjects on TREMFYA and 372 subjects on placebo). Of the 748 subjects who received TREMFYA, 375 subjects received TREMFYA 100 mg at Week 0, Week 4, and every 8 weeks thereafter and 373 subjects received TREMFYA 100 mg every 4 weeks. The overall safety profile observed in subjects with psoriatic arthritis treated with TREMFYA is generally consistent with the safety profile in subjects with plaque psoriasis with the addition of bronchitis and neutrophil count decreased. In the 24-week placebo-controlled period, combined across the two studies, bronchitis occurred in 1.6% of subjects in the TREMFYA q8w group and 2.9% of subjects in the TREMFYA q4w group compared to 1.1% of subjects in the placebo group. Neutrophil count decreased occurred in 0.3% of subjects in the TREMFYA q8w and 1.6% of subjects in the TREMFYA q4w group compared to 0% of subjects in the placebo group. The majority of events of neutrophil count decreased were mild, transient, not associated with infection and did not lead to discontinuation.

Ulcerative Colitis

TREMFYA was studied up to 12 weeks in subjects with moderately to severely active ulcerative colitis in a randomized, double-blind, placebo-controlled induction study (UC1) and a randomized, double-blind, placebo controlled, induction dose-finding study (UC3; NCT04033445). Long-term safety up to 44 weeks was evaluated in subjects who responded to induction therapy in a randomized, double-blind, placebo-controlled maintenance study (UC2) *[see Clinical Studies (14.3)]*.

In the induction studies (UC1 and UC3), 522 subjects received at least one dose of the TREMFYA intravenous induction regimen (i.e., 200 mg at Week 0, Week 4, and Week 8). Clinical response was defined as a decrease in modified Mayo score (mMS) of ≥30% and ≥2 points from baseline with either a ≥1 decrease from baseline in rectal bleeding subscore (RBS) or RBS of 0 or 1. In the maintenance study (UC2), subjects who achieved clinical response after 12 weeks of TREMFYA intravenous induction treatment were randomized and received either TREMFYA 100 mg every 8 weeks (with the first dose given at Week 4 of UC2) or TREMFYA 200 mg every 4 weeks (with the first dose given at Week 0 of UC2), by subcutaneous (SC) injection for up to an additional 44 weeks.

Respiratory tract infections occurred in ≥2% of subjects treated with TREMFYA and at a higher rate than placebo (8.8% TREMFYA-treated subjects vs. 7.3% placebo-treated subjects) through Week 12 in the induction studies (UC1 and UC3). Respiratory tract infections included COVID-19, influenza, nasopharyngitis, respiratory tract infection, upper respiratory tract infection, and viral respiratory tract infection.

Adverse reactions that occurred in ≥3% of subjects treated with TREMFYA and at a higher rate than placebo through Week 44 in the maintenance study (UC2) are shown in Table 2.

Table 2: Adverse Reactions Occurring in ≥3% of Subjects through Week 44 in UC2

	TREMFYA[a] 100 mg Subcutaneous Injection N=186 n (%)	TREMFYA[a] 200 mg Subcutaneous Injection N=190 n (%)	Placebo N=192 n (%)
Injection site reactions[b]	2 (1.1)	17 (8.9)[c]	2 (1)
Arthralgia	8 (4.3)	15 (7.9)	13 (6.8)
Upper respiratory tract infection	6 (3.2)	13 (6.8)	8 (4.2)

[a] Subjects receiving TREMFYA 100 mg at Week 16 and every 8 weeks thereafter or TREMFYA 200 mg at Week 12 and every 4 weeks thereafter.
[b] Injection site reactions include administration site pain, injection site hematoma, injection site hemorrhage, injection site hypersensitivity, injection site erythema, injection site pain, injection site pruritus, injection site rash, injection site reaction, and injection site urticaria.
[c] TREMFYA 200 mg was administered as two 100 mg injections.

6.2 Postmarketing Experience

The following adverse reactions have been reported during post-approval of TREMFYA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to TREMFYA exposure.

Immune system disorders: Hypersensitivity, including anaphylaxis *[see Warnings and Precautions (5.1)]*

Skin and subcutaneous tissue disorders: Rash *[see Warnings and Precautions (5.1)]*

7 DRUG INTERACTIONS

7.1 CYP450 Substrates

The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNFα, interferon) during chronic inflammation.

Results from an exploratory drug-drug interaction study in subjects with moderate-to-severe plaque psoriasis suggested a low potential for clinically relevant drug interactions for drugs metabolized by CYP3A4, CYP2C9, CYP2C19 and CYP1A2 but the interaction potential cannot be ruled out for drugs metabolized by CYP2D6. However, the results were highly variable because of the limited number of subjects in the study.

Upon initiation of TREMFYA in patients who are receiving concomitant CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for therapeutic effect or drug concentration and consider dosage adjustment as needed *[see Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy registry that monitors pregnancy outcomes in women exposed to TREMFYA during pregnancy. Patients should be encouraged to enroll in the registry by visiting www.mothertobaby.org/ongoing-study/tremfya-guselkumab, by calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu.

Risk Summary

Available data from literature, post-marketing reports, and ongoing pregnancy registry with TREMFYA use in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, TREMFYA may be transmitted from the mother to the developing fetus.

In a combined embryofetal development and pre- and post-natal development study, no adverse developmental effects were observed in infants born to pregnant monkeys after subcutaneous administration of guselkumab during organogenesis through parturition at doses up to 18 times the exposure (AUC) in humans administered 200 mg intravenously and 32 times the exposure (AUC) to the 200 mg dose given subcutaneously. Neonatal deaths in monkeys were observed at 4 to 18 times the exposure (AUC) in humans administered 200 mg intravenously and 7 to 32 times the exposure (AUC) to the 200 mg dose given subcutaneously *(see Data)*. The clinical significance of these nonclinical findings is unknown.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and Embryo/Fetal Risk

Published data suggest that the risk of adverse pregnancy outcomes in women with inflammatory bowel disease (IBD) is associated with increased disease activity. Adverse pregnancy outcomes include preterm delivery (before 37 weeks gestation), low birth weight (less than 2500 g) infants, and small for gestational age at birth.

Data

Animal Data

In a combined embryofetal development and pre- and post-natal development study, pregnant cynomolgus monkeys were administered weekly subcutaneous doses of guselkumab from the beginning of organogenesis to parturition at a dose (50 mg/kg) resulting in exposures (AUC) 18 times the exposure in humans administered 200 mg intravenously and 32 times the human exposure at 200 mg given subcutaneously. Neonatal deaths occurred in the offspring of one control monkey, three monkeys administered guselkumab at 10 mg/kg/week (4 times the exposure (AUC) in humans administered 200 mg intravenously and 7 times the exposure (AUC) at 200 mg given subcutaneously) and three monkeys administered guselkumab at 50 mg/kg/week (18 times the exposure (AUC) in humans administered 200 mg intravenously and 32 times the exposure (AUC) following a 200 mg subcutaneous dose). The clinical significance of these findings is unknown. No guselkumab-related effects on functional or immunological development were observed in the infants from birth through 6 months of age.

8.2 Lactation

Risk Summary

There are no data on the presence of guselkumab in human milk, the effects on the breastfed infant, or the effects on milk production. Guselkumab was not detected in the milk of lactating cynomolgus monkeys. Endogenous maternal IgG and monoclonal antibodies are transferred into human milk. The effects of local gastrointestinal exposure and the extent of systemic exposure in the breastfed infant to guselkumab are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TREMFYA and any potential adverse effects on the breastfed infant from TREMFYA or from the underlying maternal condition.

8.4 Pediatric Use

The safety and efficacy of TREMFYA in pediatric patients (less than 18 years of age) have not been established.

8.5 Geriatric Use

Of the 4303 subjects with plaque psoriasis, psoriatic arthritis, or ulcerative colitis exposed to TREMFYA, a total of 240 subjects were 65 years or older, and 23 subjects were 75 years or older. Clinical studies of TREMFYA, within each indication, did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

No clinically meaningful differences in the pharmacokinetics of guselkumab were observed based on age *[see Clinical Pharmacology (12.3)]*.

TREMFYA® (guselkumab)

11 DESCRIPTION

Guselkumab, an interleukin-23 antagonist, is a human immunoglobulin G1 lambda (IgG1λ) monoclonal antibody. Guselkumab is produced in a mammalian cell line using recombinant DNA technology and has an approximate molecular weight of approximately 147 kDa.

TREMFYA® (guselkumab) injection is a sterile, preservative free, clear, and colorless to light yellow solution.

TREMFYA for Subcutaneous Injection

Available as a 100 mg/mL solution in a 1 mL or 2 mL glass prefilled syringe, in a 2 mL prefilled pen, or in a 1 mL One-Press patient-controlled injector for subcutaneous use.

Each TREMFYA 1 mL prefilled syringe or One-Press patient-controlled injector delivers 100 mg guselkumab, L-histidine (0.6 mg), L-histidine monohydrochloride monohydrate (1.5 mg), polysorbate 80 (0.5 mg), sucrose (79 mg) and water for injection at pH 5.8.

Each TREMFYA 2 mL prefilled syringe or prefilled pen (TREMFYA PEN) delivers 200 mg guselkumab, L-histidine (1.2 mg), L-histidine monohydrochloride monohydrate (3 mg), polysorbate 80 (1 mg), sucrose (158 mg) and water for injection at pH 5.8.

TREMFYA for Intravenous Infusion

Available as 10 mg/mL solution in a 20 mL single-dose vial for intravenous use.

Each TREMFYA 20 mL vial delivers 200 mg guselkumab, EDTA disodium dihydrate (0.4 mg), L-histidine (11.3 mg), L-histidine monohydrochloride monohydrate (26.6 mg), L-methionine (8 mg), polysorbate 80 (10 mg), sucrose (1700 mg) and water for injection at pH 5.8.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Guselkumab is a human monoclonal IgG1λ antibody that selectively binds to the p19 subunit of interleukin 23 (IL-23) and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Guselkumab inhibits the release of proinflammatory cytokines and chemokines.

12.2 Pharmacodynamics

In evaluated subjects with plaque psoriasis, guselkumab reduced serum levels of IL-17A, IL-17F and IL-22 relative to pre-treatment levels based on exploratory analyses of the pharmacodynamic markers.

In evaluated subjects with psoriatic arthritis, serum levels of acute phase proteins C-reactive protein, serum amyloid A and IL-6, and Th17 effector cytokines IL-17A, IL-17F and IL-22 were elevated at baseline. Serum levels of these proteins measured at Week 4 and Week 24 were decreased compared to baseline following guselkumab treatment at Week 0, Week 4 and every 8 weeks thereafter.

The relationship between these pharmacodynamic markers and the mechanism(s) by which guselkumab exerts its clinical effects is unknown.

12.3 Pharmacokinetics

Guselkumab exhibited linear pharmacokinetics in healthy subjects and subjects with plaque psoriasis following subcutaneous injections. In subjects with plaque psoriasis, following subcutaneous administration of 100 mg of TREMFYA at Weeks 0 and 4, and every 8 weeks thereafter, mean steady-state trough serum guselkumab concentration was approximately 1.2 mcg/mL.

The pharmacokinetics of guselkumab in subjects with psoriatic arthritis was similar to that in subjects with plaque psoriasis. Following subcutaneous administration of 100 mg of TREMFYA at Weeks 0, 4, and every 8 weeks thereafter, mean steady-state trough serum guselkumab concentration was approximately 1.2 mcg/mL.

Following subcutaneous maintenance dosing of 100 mg TREMFYA every 8 weeks or 200 mg TREMFYA every 4 weeks in subjects with ulcerative colitis, mean steady-state trough serum guselkumab concentrations were approximately 1.4 mcg/mL and 10.7 mcg/mL, respectively.

Absorption

Following a single 100 mg subcutaneous injection in healthy subjects, guselkumab reached a mean (± SD) maximum serum concentration of 8.09 ± 3.68 mcg/mL by approximately 5.5 days post dose. The absolute bioavailability of guselkumab following a single 100 mg subcutaneous injection was estimated to be approximately 49% in healthy subjects.

Following the recommended intravenous induction dose regimen of TREMFYA 200 mg at Weeks 0, 4, and 8, mean (± SD) peak serum guselkumab concentration at Week 8 was 68.3 ± 17.3 mcg/mL in subjects with ulcerative colitis.

Distribution

In subjects with plaque psoriasis, apparent volume of distribution was 13.5 L. In subjects with ulcerative colitis, apparent volume of distribution at steady-state was 10.1 L.

Elimination

Apparent clearance in subjects with plaque psoriasis was 0.516 L/day. Mean half-life of guselkumab was approximately 15 to 18 days in subjects with plaque psoriasis across trials.

The apparent clearance in subjects with ulcerative colitis was 0.531 L/day. Mean half-life of guselkumab was approximately 17 days in subjects with ulcerative colitis.

Metabolism

The exact pathway through which guselkumab is metabolized has not been characterized. As a human IgG monoclonal antibody, guselkumab is expected to be degraded into small peptides and amino acids via catabolic pathways in the same manner as endogenous IgG.

Specific Populations

No apparent differences in clearance were observed in subjects ≥ 65 years of age compared to subjects < 65 years of age, suggesting no dose adjustment is needed for elderly subjects. Clearance and volume of distribution of guselkumab increases as body weight increases, however, observed clinical trial data indicate that dose adjustment for body weight is not warranted. No specific trials have been conducted to determine the effect of renal or hepatic impairment on the pharmacokinetics of guselkumab.

Drug Interactions

Population pharmacokinetic analyses indicated that concomitant use of NSAIDs, oral corticosteroids and conventional DMARDs such as methotrexate (MTX), azathioprine (AZA), and 6-mercaptopurine (6-MP), did not affect the clearance of guselkumab.

Cytochrome P450 Substrates

The effects of guselkumab on the pharmacokinetics of midazolam (metabolized by CYP3A4), warfarin (metabolized by CYP2C9), omeprazole (metabolized by CYP2C19), dextromethorphan (metabolized by CYP2D6), and caffeine (metabolized by CYP1A2) were evaluated in an exploratory study with 6 to 12 evaluable subjects with moderate-to-severe plaque psoriasis. Changes in AUC_{inf} of midazolam, S-warfarin, omeprazole, and caffeine after a single dose of guselkumab were not clinically relevant. For dextromethorphan, changes in AUC_{inf} after guselkumab were not clinically relevant in 9 out of 10 subjects; however, a 2.9-fold change in AUC_{inf} was observed in one individual *[see Drug Interactions (7.1)]*.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of guselkumab or of other guselkumab products.

Plaque Psoriasis

Up to Week 52, approximately 6% of subjects treated with TREMFYA developed antidrug antibodies. Of the subjects who developed antidrug antibodies, approximately 7% had antibodies that were classified as neutralizing antibodies. Among the 46 subjects who developed antibodies to guselkumab and had evaluable data, 21 subjects exhibited lower trough levels of guselkumab, including one subjects who experienced loss of efficacy after developing high antibody titers. Up to Week 156, approximately 9% of subjects treated with TREMFYA developed antidrug antibodies and of these subjects approximately 6% were classified as neutralizing antibodies. However, antibodies to guselkumab were generally not associated with changes in clinical response or development of injection-site reactions.

Psoriatic Arthritis

Up to Week 24, 2% (n=15) of subjects treated with TREMFYA developed antidrug antibodies. Of these subjects, 1 had antibodies that were classified as neutralizing antibodies. Overall, the small number of subjects who were positive for antibodies to guselkumab limits definitive conclusion of the effect of immunogenicity on the pharmacokinetics, efficacy and safety of guselkumab.

Ulcerative Colitis

Up to Week 56 in Studies UC1, UC2 and UC3, 11% (n=48) of subjects treated with TREMFYA at the recommended dosage developed antidrug antibodies. Of these subjects who tested positive for anti-guselkumab antibodies and were evaluable for neutralizing antibodies, 16% (n=6) had antibodies that were classified as neutralizing antibodies. Most of the subjects who were positive for antibodies to guselkumab had low titers. Two subjects with the highest antibody titers exhibited low trough levels of guselkumab. There was no identified clinically significant effect of antidrug antibodies on injection site reactions, or effectiveness of guselkumab, over the treatment duration of 56 weeks.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to evaluate the carcinogenic or mutagenic potential of TREMFYA.

No effects on fertility parameters were observed after male guinea pigs were subcutaneously administered guselkumab at a dose of 25 mg/kg twice weekly (6 times the exposure (AUC) in humans administered 200 mg intravenously and 10 times the exposure (AUC) at the 200 mg subcutaneous dose).

No effects on fertility parameters were observed after female guinea pigs were subcutaneously administered guselkumab at doses up to 100 mg/kg twice weekly (12 times the exposure (AUC) in humans administered 200 mg intravenously and 21 times the exposure (AUC) at the 200 mg subcutaneous dose).

14 CLINICAL STUDIES

14.1 Plaque Psoriasis

Four multicenter, randomized, double-blind trials (PsO1 [NCT02207231], PsO2 [NCT02207244], PsO3 [NCT02203032], and PsO4 [NCT02905331]) enrolled subjects

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18 years of age and older with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy. Subjects had an Investigator's Global Assessment (IGA) score of ≥3 ("moderate") on a 5-point scale of overall disease severity, a Psoriasis Area and Severity Index (PASI) score ≥12, and a minimum affected body surface area (BSA) of 10%. Subjects with guttate, erythrodermic, or pustular psoriasis were excluded.

Trials PsO1 and PsO2

In PsO1 and PsO2, 1443 subjects were randomized to either TREMFYA (100 mg at Weeks 0 and 4 and every 8 weeks thereafter) administered with a prefilled syringe, placebo or U.S. licensed adalimumab (80 mg at Week 0 and 40 mg at Week 1, followed by 40 mg every other week thereafter).

Both trials assessed the responses at Week 16 compared to placebo for the two co-primary endpoints:

- the proportion of subjects who achieved an IGA score of 0 ("cleared") or 1 ("minimal");
- the proportion of subjects who achieved at least a 90% reduction from baseline in the PASI composite score (PASI 90).

Comparisons between TREMFYA and U.S. licensed adalimumab were secondary endpoints at the following time points:

- at Week 16 (PsO1 and PsO2), the proportions of subjects who achieved an IGA score of 0 or 1, a PASI 90, and a PASI 75 response;
- at Week 24 (PsO1 and PsO2), and at Week 48 (PsO1), the proportions of subjects achieving an IGA score of 0, an IGA score of 0 or 1, and a PASI 90 response.

Other evaluated outcomes included improvement in psoriasis symptoms assessed on the Psoriasis Symptoms and Signs Diary (PSSD) and improvements in psoriasis of the scalp at Week 16.

In both trials, subjects were predominantly men and white, with a mean age of 44 years and a mean weight of 90 kg. At baseline, subjects had a median affected BSA of approximately 21%, a median PASI score of 19, and 18% had a history of psoriatic arthritis. Approximately 24% of subjects had an IGA score of severe. In both trials, 23% had received prior biologic systemic therapy.

Clinical Response

Table 3 presents the efficacy results at Week 16 in PsO1 and PsO2.

Table 3: Efficacy Results at Week 16 in Adults with Plaque Psoriasis (NRI[a])

	PsO1		PsO2	
Endpoint	**TREMFYA (N=329) n (%)**	**Placebo (N=174) n (%)**	**TREMFYA (N=496) n (%)**	**Placebo (N=248) n (%)**
IGA response of 0/1[b,c]	280 (85)	12 (7)	417 (84)	21 (8)
PASI 90 response[b]	241 (73)	5 (3)	347 (70)	6 (2)

[a] NRI = Non-Responder Imputation
[b] Co-Primary Endpoints
[c] IGA response of 0 (cleared) or 1 (minimal)

Table 4 presents the results of an analysis of all the North America sites (i.e., U.S. and Canada), demonstrating superiority of TREMFYA to U.S. licensed adalimumab.

Table 4: Efficacy Results in Adults with Plaque Psoriasis (NRI[a])

	PsO1		PsO2	
Endpoint	**TREMFYA (N=115)[b] n (%)**	**Adalimumab[c] (N=115)[b] n (%)**	**TREMFYA (N=160)[b] n (%)**	**Adalimumab[c] (N=81)[b] n (%)**
IGA response of 0/1 (cleared or minimal)				
Week 16	97 (84)	70 (61)	119 (74)	50 (62)
Week 24	97 (84)	62 (54)	119 (74)	46 (57)
Week 48	91 (79)	62 (54)	NA	NA
IGA response of 0 (cleared)				
Week 24	61 (53)	27 (23)	76 (48)	23 (28)
Week 48	54 (47)	28 (24)	NA	NA
PASI 75 response				
Week 16	105 (91)	80 (70)	132 (83)	51 (63)
PASI 90 response				
Week 16	84 (73)	47 (41)	102 (64)	34 (42)
Week 24	92 (80)	51 (44)	113 (71)	41 (51)
Week 48	84 (73)	53 (46)	NA	NA

[a] NRI = Non-Responder Imputation
[b] Subjects from sites in the United States and Canada
[c] U.S. licensed adalimumab

An improvement was seen in psoriasis involving the scalp in subjects randomized to TREMFYA compared to placebo at Week 16.

Examination of age, gender, race, body weight, and previous treatment with systemic or biologic agents did not identify differences in response to TREMFYA among these subgroups.

Maintenance and Durability of Response

To evaluate maintenance and durability of response (PsO2), subjects randomized to TREMFYA at Week 0 and who were PASI 90 responders at Week 28 were re-randomized to either continue treatment with TREMFYA every 8 weeks or be withdrawn from therapy (i.e., receive placebo).

At Week 48, 89% of subjects who continued on TREMFYA maintained PASI 90 compared to 37% of subjects who were re-randomized to placebo and withdrawn from TREMFYA. For responders at Week 28 who were re-randomized to placebo and withdrawn from TREMFYA, the median time to loss of PASI 90 was approximately 15 weeks.

Patient Reported Outcomes

Greater improvements in symptoms of psoriasis (itch, pain, stinging, burning and skin tightness) at Week 16 in TREMFYA compared to placebo were observed in both trials based on the Psoriasis Symptoms and Signs Diary (PSSD). Greater proportions of subjects on TREMFYA compared to U.S. licensed adalimumab achieved a PSSD symptom score of 0 (symptom-free) at Week 24 in both trials.

Trial PsO3

PsO3 [NCT02203032] evaluated the efficacy of 24 weeks of treatment with TREMFYA in subjects (N=268) who had not achieved an adequate response, defined as IGA ≥2 at Week 16 after initial treatment with U.S. licensed ustekinumab (dosed 45 mg or 90 mg according to the subject's baseline weight at Week 0 and Week 4). These subjects were randomized to either continue with U.S. licensed ustekinumab treatment every 12 weeks or switch to TREMFYA 100 mg at Weeks 16, 20, and every 8 weeks thereafter. Baseline characteristics for randomized subjects were similar to those observed in PsO1 and PsO2.

In subjects with an inadequate response (IGA ≥2 at Week 16 to U.S. licensed ustekinumab), greater proportions of subjects on TREMFYA compared to U.S. licensed ustekinumab achieved an IGA score of 0 or 1 with a ≥2 grade improvement at Week 28 (31% vs. 14%, respectively; 12 weeks after randomization).

Trial PsO4

PsO4 [NCT02905331] evaluated the efficacy, safety, and pharmacokinetics of TREMFYA administered with the One-Press injector. In this study, 78 subjects were randomized to receive either TREMFYA (100 mg at Weeks 0 and 4 and every 8 weeks thereafter) [N=62], or placebo [N=16]. Baseline characteristics for subjects were comparable to those observed in PsO1 and PsO2. The co-primary endpoints were the same as those for PsO1 and PsO2. Secondary endpoints included the proportion of subjects who achieved an IGA score of 0 at Week 16 and the proportion of subjects who achieved a PASI 100 response at Week 16.

A greater proportion of subjects in the guselkumab group achieved an IGA score of 0 or 1 or a PASI 90 response at Week 16 (81% and 76%, respectively) than in the placebo group (0% for both endpoints). The proportion of subjects who achieved an IGA score of 0 at Week 16 was higher in the guselkumab group compared to the placebo group (56% vs. 0%). The proportion of subjects who achieved a PASI 100 response at Week 16 was higher in the guselkumab group compared to the placebo group (50% vs. 0%).

14.2 Psoriatic Arthritis

The safety and efficacy of TREMFYA were assessed in 1120 subjects in 2 randomized, double-blind, placebo-controlled trials (PsA1 [NCT03162796] and PsA2 [NCT03158285]) in adult subjects with active psoriatic arthritis (PsA) (≥3 swollen joints, ≥3 tender joints, and a C-reactive protein (CRP) level of ≥0.3 mg/dL in PsA1 and ≥5 swollen joints, ≥5 tender joints, and a CRP level of ≥0.6 mg/dL in PsA2) who had inadequate response to standard therapies (e.g., conventional DMARDs [cDMARDs]), apremilast, or nonsteroidal anti-inflammatory drugs [NSAIDs]). Subjects in these trials had a diagnosis of PsA for at least 6 months based on the Classification criteria for Psoriatic Arthritis (CASPAR) and a median duration of PsA of 4 years at baseline.

In PsA1 approximately 31% of subjects had been previously treated with up to 2 anti-tumor necrosis factor alpha (anti-TNFα) agents whereas in PsA2 all subjects were biologic naïve. Approximately 58% of subjects from both trials had concomitant methotrexate (MTX) use. Subjects with different subtypes of PsA were enrolled in both trials, including polyarticular arthritis with the absence of rheumatoid nodules (40%), spondylitis with peripheral arthritis (30%), asymmetric peripheral arthritis (23%), distal interphalangeal involvement (7%) and arthritis mutilans (1%). At baseline, over 65% and 42% of the subjects had enthesitis and dactylitis, respectively and 79% had ≥3% body surface area (BSA) psoriasis skin involvement.

PsA1 evaluated 381 subjects who were treated with placebo SC, TREMFYA 100 mg SC at Weeks 0, 4 and every 8 weeks (q8w) thereafter, or TREMFYA 100 mg SC every 4 weeks (q4w). PsA2 evaluated 739 subjects who were treated with placebo SC, TREMFYA 100 mg SC at Weeks 0, 4 and q8w thereafter, or TREMFYA 100 mg SC q4w. The primary endpoint in both trials was the percentage of subjects achieving an ACR20 response at Week 24.

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Clinical Response

In both trials, subjects treated with TREMFYA 100 mg q8w demonstrated a greater clinical response including ACR20, compared to placebo at Week 24 (Tables 5 and 6). Similar responses were seen regardless of prior anti-TNFα exposure in PsA1, and in both trials similar responses were seen regardless of concomitant cDMARD use, previous treatment with cDMARDs, gender and body weight.

Table 5: Percent of Subjects with ACR Responses in PsA1

	Placebo (N=126)	TREMFYA 100 mg q8w (N=127)	
	Response Rate	Response Rate	Difference from Placebo (95% CI)
ACR 20 response[a]			
Week 16	25%	52%	27 (15, 38)
Week 24	22%	52%	30 (19, 41)
ACR 50 response[a]			
Week 16	13%	23%	10 (1, 19)
Week 24	9%	30%	21 (12, 31)
ACR 70 response[a]			
Week 16	6%	8%	2 (-4, 8)
Week 24	6%	12%	6 (-0.3, 13)

[a] Subjects with missing data at a visit were imputed as non-responders at that visit. Subjects who met escape criteria (less than 5% improvement in both tender and swollen joint counts) at Week 16 were allowed to initiate or increase the dose of the permitted concomitant medication and remained on the randomized group. Subjects who initiated or increased the dose of non-biologic DMARD or oral corticosteroids over baseline, discontinued study/study medication or initiated protocol prohibited medications/therapies for PsA prior to a visit were considered non-responders at that visit.

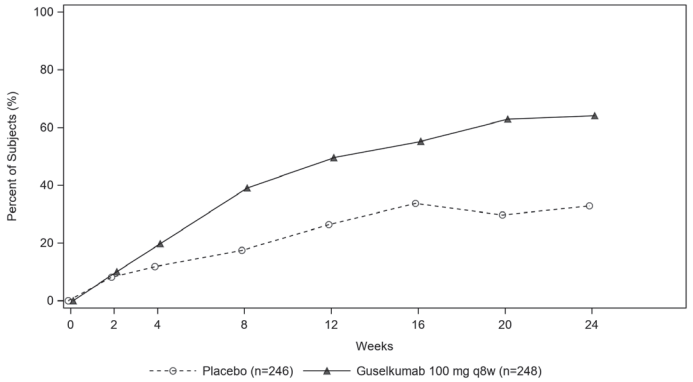
Table 6: Percent of Subjects with ACR Responses in PsA2

	Placebo (N=246)	TREMFYA 100 mg q8w (N=248)	
	Response Rate	Response Rate	Difference from Placebo (95% CI)
ACR 20 response[a]			
Week 16	34%	55%	22 (13, 30)
Week 24	33%	64%	31 (23, 40)
ACR 50 response[a]			
Week 16	9%	29%	19 (13, 26)
Week 24	14%	32%	17 (10, 24)
ACR 70 response[a]			
Week 16	1%	14%	13 (9, 17)
Week 24	4%	19%	15 (9, 20)

[a] Subjects with missing data at a visit were imputed as non-responders at that visit. Subjects who met escape criteria (less than 5% improvement in both tender and swollen joint counts) at Week 16 were allowed to initiate or increase the dose of the permitted concomitant medication and remained on the randomized group. Subjects who initiated or increased the dose of non-biologic DMARD or oral corticosteroids over baseline, discontinued study/study medication or initiated protocol prohibited medications/therapies for PsA prior to a visit were considered non-responders at that visit.

The percentage of subjects achieving ACR20 response in PsA2 by visit is shown in Figure 1.

Figure 1: Subjects Achieving ACR 20 Response by Visit Through Week 24 in PsA2



The results of the components of the ACR response criteria are shown in Table 7.

Table 7: Mean change (SD[a]) from Baseline in ACR Component Scores at Week 16 and 24 based on Observed Data

	PsA1		PsA2	
	Placebo (N=126)	**TREMFYA 100 mg q8w (N=127)**	**Placebo N=246**	**TREMFYA 100 mg q8w (N=248)**
No. of Swollen Joints				
Baseline	10.1 (7.1)	10.9 (9.3)	12.3 (6.9)	11.7 (6.8)
Mean change at Week 16	-4.2 (7.0)	-7.3 (7.0)	-5.8 (7.1)	-7.2 (6.0)
Mean change at Week 24	-5.1 (6.9)	-7.3 (8.0)	-6.4 (7.2)	-8.1 (6.1)
No. of Tender Joints				
Baseline	19.8 (14.4)	20.2 (14.5)	21.6 (13.1)	19.8 (11.9)
Mean change at Week 16	-4.5 (10.8)	-10.2 (10.4)	-6.8 (10.5)	-9.0 (9.4)
Mean change at Week 24	-6.8 (13.0)	-10.5 (12.0)	-7.3 (11.2)	-10.4 (9.5)
Patient's Assessment of Pain[b]				
Baseline	5.8 (2.2)	6.0 (2.1)	6.3 (1.8)	6.3 (2.0)
Mean change at Week 16	-0.8 (2.3)	-1.7 (2.4)	-0.9 (2.3)	-2.2 (2.5)
Mean change at Week 24	-0.7 (2.4)	-2.2 (2.6)	-1.1 (2.4)	-2.5 (2.5)
Patient Global Assessment[b]				
Baseline	6.1 (2.2)	6.5 (2.0)	6.5 (1.8)	6.5 (1.9)
Mean change at Week 16	-1.0 (2.3)	-2.0 (2.6)	-1.0 (2.3)	-2.3 (2.6)
Mean change at Week 24	-0.9 (2.5)	-2.5 (2.7)	-1.2 (2.6)	-2.5 (2.5)
Physician Global Assessment[b]				
Baseline	6.3 (1.7)	6.2 (1.7)	6.7 (1.5)	6.6 (1.6)
Mean change at Week 16	-1.9 (2.2)	-2.9 (2.4)	-2.1 (2.2)	-3.5 (2.3)
Mean change at Week 24	-2.2 (2.3)	-3.5 (2.4)	-2.5 (2.3)	-3.8 (2.3)
Disability Index (HAQ-DI)[c]				
Baseline	1.2 (0.7)	1.2 (0.6)	1.3 (0.6)	1.3 (0.6)
Mean change at Week 16	-0.1 (0.5)	-0.3 (0.5)	-0.1 (0.5)	-0.3 (0.5)
Mean change at Week 24	-0.1 (0.5)	-0.3 (0.6)	-0.2 (0.5)	-0.4 (0.5)
CRP (mg/dL)				
Baseline	1.4 (1.9)	1.6 (2.4)	2.1 (2.7)	2.0 (2.4)
Mean change at Week 16	-0.2 (1.5)	-0.6 (2.2)	-0.6 (2.5)	-1.0 (2.2)
Mean change at Week 24	-0.0 (2.8)	-0.7 (2.1)	-0.5 (2.5)	-1.1 (2.2)

[a] SD= standard deviation

[b] Assessment based on Visual Analog Scale (cm) with the left end indicating "no pain" (for patient's assessment of pain), "very well" (for patient global assessment), or "no arthritis activity" (for physician global assessment) and the right end indicating "the worst possible pain" (for patient assessment of pain), "poor" (for patient global assessment), or "extremely active arthritis (for physician global assessment).

[c] Disability Index of the Health Assessment Questionnaire; 0 = no difficulty to 3 = inability to perform, measures the patient's ability to perform the following: dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living

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Treatment with TREMFYA resulted in an improvement in the skin manifestations of psoriasis in subjects with PsA.

Treatment with TREMFYA resulted in improvement in dactylitis and enthesitis in subjects with pre-existing dactylitis or enthesitis.

Physical Function

TREMFYA treated subjects in the TREMFYA 100 mg q8w group in both PsA1 and PsA2 showed greater mean improvement from baseline in physical function compared to subjects treated with placebo as assessed by the Health Assessment Questionnaire-Disability Index (HAQ-DI) at Weeks 16 and 24. In both studies, the proportion of HAQ-DI responders (≥0.35 improvement in HAQ-DI score) was greater in the TREMFYA q8w dose group compared to placebo at Weeks 16 and 24.

Other Health-Related Outcomes

General health status was assessed by the Short Form health survey (SF-36). At Week 24, subjects in the TREMFYA 100 mg q8w dose group in both PsA1 and PsA2 showed greater improvement from baseline in the SF-36 physical component summary (PCS) compared with placebo. There was not a statistically significant improvement observed in the SF-36 MCS. At Week 24, there was numerical improvement in the physical functioning, role-physical, bodily-pain, general health, social-functioning and vitality domains but not in the role-emotional and mental health domains. Fatigue was assessed by the Functional Assessment of Chronic Illness Therapy-Fatigue score (FACIT-F) in Studies PsA1 and PsA2. Treatment with TREMFYA resulted in improvement in fatigue as measured by FACIT-F.

14.3 Ulcerative Colitis

Induction Trial: UC1

In the 12-week induction study (UC1; NCT04033445), 701 subjects with moderately to severely active ulcerative colitis were randomized 3:2 to receive either TREMFYA 200 mg or placebo by intravenous infusion at Week 0, Week 4, and Week 8. Disease activity was assessed by the modified Mayo score (mMS), a 3-component Mayo score (0-9) which consists of the following subscores (0 to 3 for each subscore): stool frequency (SFS), rectal bleeding (RBS), and findings on centrally reviewed endoscopy (ES). An ES of 2 was defined by marked erythema, lack of vascular pattern, friability, and/or erosions; an ES of 3 was defined by spontaneous bleeding and ulceration. Enrolled subjects with a mMS between 5 and 9 and an ES of 2 or 3 were classified as having moderately to severely active ulcerative colitis. Subjects with inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine), biologic therapy (TNF blockers, vedolizumab), and/or Janus kinase (JAK) inhibitors were enrolled.

At baseline in UC1, the median mMS was 7, 64% of subjects had severely active disease (mMS ≥7), and 68% of subjects had an ES of 3. In UC1, 49% of subjects had previously failed (inadequate response, loss of response, or intolerance) treatment with at least one biologic therapy and/or JAK inhibitor, 48% were biologic and JAK inhibitor naïve, and 3% had previously received but not failed a biologic or JAK inhibitor. The median age was 39 years (ranging from 18 to 79 years); 43% were female; and 72% identified as White, 21% as Asian, 1% as Black or African American, <1% as American Indian or Alaskan Native, and <1% as multiple racial groups.

Enrolled subjects were permitted to use stable doses of oral aminosalicylates, immunomodulators (azathioprine, 6-mercaptopurine, methotrexate), and/or oral corticosteroids (up to 20 mg/day prednisone or equivalent). At baseline, 72% of subjects were receiving aminosalicylates, 21% of subjects were receiving immunomodulators, and 43% of subjects were receiving corticosteroids. Concomitant biologic therapies or JAK inhibitors were not permitted.

In UC1, the primary endpoint was clinical remission at Week 12 as defined by the mMS. Secondary endpoints at Week 12 included endoscopic improvement, clinical response, and histologic endoscopic mucosal improvement (see Table 8).

Table 8: Proportion of Subjects with Ulcerative Colitis Meeting Efficacy Endpoints at Week 12 in UC1

Endpoint	**Placebo**	**TREMFYA 200 mg Intravenous Infusion[a]**	**Treatment Difference (95% CI)**
Clinical remission[b]			
Total Population	N=280 8%	N=421 23%	15% (10%, 20%)[c]
Prior biologic and/or JAK inhibitor failure[d]	N=136 4%	N=208 13%	
Without prior biologic or JAK inhibitor failure[e]	N=144 12%	N=213 32%	
Endoscopic improvement[f]			
Total Population	N=280 11%	N=421 27%	16% (10%, 21%)[c]
Prior biologic and/or JAK inhibitor failure[d]	N=136 5%	N=208 15%	
Without prior biologic or JAK inhibitor failure[e]	N=144 17%	N=213 38%	

Table 8: Proportion of Subjects with Ulcerative Colitis Meeting Efficacy Endpoints at Week 12 in UC1 (continued)

Endpoint	Placebo	TREMFYA 200 mg Intravenous Infusion[a]	Treatment Difference (95% CI)
Clinical response[g]			
Total Population	N=280 28%	N=421 62%	34% (27%, 41%)[c]
Prior biologic and/or JAK inhibitor failure[d]	N=136 20%	N=208 51%	
Without prior biologic or JAK inhibitor failure[e]	N=144 35%	N=213 71%	
Histologic endoscopic mucosal improvement (HEMI)[h]			
Total Population	N=280 8%	N=421 24%	16% (11%, 21%)[c]
Prior biologic and/or JAK inhibitor failure[d]	N=136 4%	N=208 13%	
Without prior biologic or JAK inhibitor failure[e]	N=144 10%	N=213 33%	

[a] TREMFYA 200 mg as an intravenous infusion at Week 0, Week 4, and Week 8
[b] A stool frequency subscore of 0 or 1 and not increased from baseline, a rectal bleeding subscore of 0, and an endoscopy subscore of 0 or 1 with no friability
[c] p <0.001, adjusted treatment difference (95% CI) based on Cochran-Mantel-Haenszel method (adjusted for stratification factors: biologic and/or JAK-inhibitor failure status and concomitant use of corticosteroids at baseline)
[d] Includes inadequate response, loss of response, or intolerance to biologic therapy (TNF blockers, vedolizumab) and/or a Janus kinase (JAK) inhibitor for ulcerative colitis
[e] Includes subjects that were biologic and/or JAK inhibitor naïve and subjects with biologic and/or JAK inhibitor exposure who did not meet criteria for failure. Of these, 7 subjects in the placebo group and 11 subjects in the TREMFYA group were previously exposed to, but did not fail, a biologic or JAK inhibitor
[f] An endoscopy subscore of 0 or 1 with no friability
[g] Decrease from induction baseline in the modified Mayo score by ≥30% and ≥2 points, with either a ≥1 point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1
[h] An endoscopy subscore of 0 or 1 with no friability and Geboes score ≤3.1 (indicating neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue)

Study UC1 was not designed to evaluate the relationship of histologic endoscopic mucosal improvement at Week 12 to disease progression and long-term outcomes.

Rectal Bleeding and Stool Frequency Subscores

Decreases in rectal bleeding and stool frequency subscores were observed as early as Week 4 in subjects treated with TREMFYA compared to placebo.

Endoscopic Assessment

Normalization of the endoscopic appearance of the mucosa (endoscopic remission) was defined as ES of 0. At Week 12 of UC1, a greater proportion of subjects treated with TREMFYA compared to placebo-treated subjects achieved endoscopic remission (15% vs 5%).

Fatigue Response

In UC1, subjects treated with TREMFYA experienced a clinically meaningful improvement in fatigue, assessed by the PROMIS-Fatigue Short form 7a, at Week 12, compared to placebo-treated subjects. The effect of TREMFYA to improve fatigue after 12 weeks of induction has not been established.

Maintenance Trial: UC2

The maintenance trial (UC2) evaluated 568 subjects who received one of two intravenous TREMFYA induction regimens, including the recommended 200 mg regimen, for 12 weeks in Studies UC1 or UC3 (induction dose-finding study) and demonstrated clinical response per mMS after 12 weeks. Subjects were re-randomized to receive a subcutaneous maintenance regimen of either TREMFYA 100 mg every 8 weeks, TREMFYA 200 mg every 4 weeks, or placebo for up to an additional 44 weeks.

In UC2, 42% of subjects had failed (inadequate response, loss of response, or intolerance) treatment with one or more biologics or JAK inhibitors.

The primary endpoint was clinical remission at Week 44 defined by mMS. Secondary endpoints included corticosteroid-free clinical remission, endoscopic improvement, histologic endoscopic mucosal improvement, all at Week 44 and maintenance of clinical remission at Week 44 in subjects who achieved clinical remission 12 weeks after intravenous TREMFYA induction treatment (see Table 9).

TREMFYA® (guselkumab)

Table 9: Proportion of Subjects with Ulcerative Colitis Meeting Efficacy Endpoints at Week 44 in UC2

Endpoint	Placebo	TREMFYA 100 mg Every 8 Weeks Subcutaneous Injection[a]	TREMFYA 200 mg Every 4 Weeks Subcutaneous Injection[b]	Treatment Difference vs Placebo (95% CI)	
				TREMFYA 100 mg	TREMFYA 200 mg
Clinical remission[c]					
Total population[d]	N=190 19%	N=188 45%	N=190 50%	25% (16%, 34%)[e]	30% (21%, 38%)[e]
Prior biologic and/or JAK inhibitor failure[f]	N=75 8%	N=77 40%	N=88 40%		
Without prior biologic or JAK inhibitor failure[g]	N=115 26%	N=111 49%	N=102 59%		
Corticosteroid-free clinical remission[h]					
Total population[d]	N=190 18%	N=188 45%	N=190 49%	26% (17%, 34%)[e]	29% (20%, 38%)[e]
Prior biologic and/or JAK inhibitor failure[f]	N=75 7%	N=77 40%	N=88 40%		
Without prior biologic or JAK inhibitor failure[g]	N=115 26%	N=111 49%	N=102 57%		
Endoscopic improvement[i]					
Total population[d]	N=190 19%	N=188 49%	N=190 52%	30% (21%, 38%)[e]	31% (22%, 40%)[e]
Prior biologic and/or JAK inhibitor failure[f]	N=75 8%	N=77 45%	N=88 42%		
Without prior biologic or JAK inhibitor failure[g]	N=115 26%	N=111 52%	N=102 60%		
Histologic endoscopic mucosal improvement (HEMI)[j]					
Total population[d]	N=190 17%	N=188 44%	N=190 48%	26% (17%, 34%)[e]	30% (21%, 38%)[e]
Prior biologic and/or JAK inhibitor failure[f]	N=75 8%	N=77 38%	N=88 39%		
Without prior biologic or JAK inhibitor failure[g]	N=115 23%	N=111 48%	N=102 56%		
Maintenance of Clinical Remission at Week 44 in subjects who achieved clinical remission after 12 weeks of induction					
Total population[k]	N=59 34%	N=66 61%	N=69 72%	26% (9%, 43%)[l]	38% (23%, 54%)[e]
Prior biologic and/or JAK inhibitor failure[f]	N=15 27%	N=20 60%	N=18 56%		
Without prior biologic or JAK inhibitor failure[m]	N=44 36%	N=46 61%	N=51 78%		

[a] TREMFYA 100 mg as a subcutaneous injection every 8 weeks after the induction regimen
[b] TREMFYA 200 mg as a subcutaneous injection every 4 weeks after the induction regimen
[c] A stool frequency subscore of 0 or 1 and not increased from induction baseline, a rectal bleeding subscore of 0, and an endoscopy subscore of 0 or 1 with no friability
[d] Subjects who achieved clinical response 12 weeks following the intravenous administration of TREMFYA in either induction study UC1 or induction dose-finding study UC3
[e] p <0.001, adjusted treatment difference (95% CI) based on Cochran-Mantel-Haenszel method adjusted for randomization stratification factors
[f] Includes inadequate response, loss of response, or intolerance to biologic therapy (TNF blockers, vedolizumab) and/or a Janus kinase (JAK) inhibitor for ulcerative colitis
[g] Includes subjects that were biologic and/or JAK inhibitor naïve and subjects with biologic and/or JAK inhibitor exposure who did not meet criteria for failure. Of these, 7 subjects in the placebo group, 6 subjects in the TREMFYA 100 mg group, and 6 subjects in the TREMFYA 200 mg group were previously exposed to, but did not fail, a biologic or JAK inhibitor
[h] Not requiring any treatment with corticosteroids for at least 8 weeks prior to week 44 and also meeting the criteria for clinical remission at week 44
[i] An endoscopy subscore of 0 or 1 with no friability
[j] An endoscopy subscore of 0 or 1 with no friability and Geboes score ≤3.1 (indicating neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue)
[k] Subjects who achieved clinical remission 12 weeks following intravenous administration of TREMFYA in either induction study UC1 or induction dose-finding study UC3
[l] p <0.01, adjusted treatment difference (95% CI) based on Cochran-Mantel-Haenszel method adjusted for randomization stratification factors
[m] Includes subjects that were biologic and/or JAK inhibitor naïve and subjects with biologic and/or JAK inhibitor exposure who did not meet criteria for failure. Of these, 3 subjects in the placebo group, 3 subjects in the TREMFYA 100 mg group, and 3 subjects in the TREMFYA 200 mg group were previously exposed to, but did not fail, a biologic or JAK inhibitor.

Study UC2 was not designed to evaluate the relationship of histologic endoscopic mucosal improvement at Week 44 to disease progression and long-term outcomes.

Endoscopic Assessment

Normalization of the endoscopic appearance of the mucosa (endoscopic remission) was defined as ES of 0. In UC2, greater proportions of subjects treated with TREMFYA 100 mg every 8 weeks or TREMFYA 200 mg every 4 weeks achieved endoscopic remission at Week 44 compared to placebo-treated subjects (35% and 34%, respectively, vs. 15%).

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

TREMFYA®/TREMFYA® PEN (guselkumab) injection is a clear and colorless to light yellow solution supplied as follows:

Subcutaneous Injection

- Carton of one 100 mg/mL single-dose One-Press patient-controlled injector (NDC: 57894-640-11)
- Carton of one 200 mg/2 mL single-dose prefilled pen (TREMFYA PEN) (NDC: 57894-651-02)
- Carton of one 100 mg/mL single-dose prefilled syringe with a 27G, half inch fixed needle assembled in a passive needle guard delivery system (NDC: 57894-640-01)
- Carton of one 200 mg/2 mL single-dose prefilled syringe with a 27G, half inch fixed needle assembled in a passive needle guard delivery system (NDC: 57894-651-22)

Intravenous Infusion

- Carton of one 200 mg/20 mL (10 mg/mL) single-dose vial (NDC: 57894-650-02)

16.2 Storage and Handling

TREMFYA is sterile and preservative-free. Discard any unused portion.

- Store in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF).
- Store in original carton until time of use.
- Protect from light until use.
- Do not freeze.
- Do not shake.
- Not made with natural rubber latex.

TREMFYA® (guselkumab)

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling *(Medication Guide and Instructions for Use)* before starting TREMFYA therapy, and each time the prescription is renewed, as there may be new information they need to know.

Hypersensitivity Reactions

Advise patients to discontinue TREMFYA and seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions (5.1)]*.

Infections

Instruct patients of the importance of communicating any history of infections to the healthcare provider and contacting their healthcare provider if they develop any symptoms of an infection *[see Warnings and Precautions (5.2)]*.

Immunizations

Advise patients treated with TREMFYA to avoid use of live vaccines *[see Warnings and Precautions (5.4)]*.

Instruction on Injection Technique

Instruct patients or caregivers to perform the first self-injection under the supervision and guidance of a qualified healthcare professional for proper training in subcutaneous injection technique. Instruct patients who are self-administering to inject the full dose of TREMFYA/TREMFYA PEN *[see Medication Guide and Instructions for Use]*.

Instruct patients or caregivers in the technique of proper needle and syringe disposal. Needles and syringes should be disposed of in a puncture-resistant container. Advise patients and caregivers not to reuse needles or syringes.

Remind patients if they forget to take their dose of TREMFYA/TREMFYA PEN to inject their dose as soon as they remember. They should then take their next dose at the appropriate scheduled time.

Pregnancy

Advise patients that there is a pregnancy registry that monitors pregnancy outcomes in patients exposed to TREMFYA during pregnancy *[see Use in Specific Populations (8.1)]*.

Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044, USA
US License No. 1864

For patent information: www.janssenpatents.com

Medication Guide

TREMFYA® (trem fye´ ah) (guselkumab) injection, for subcutaneous use

TREMFYA® (trem fye´ ah) PEN (guselkumab) injection, for subcutaneous use

TREMFYA® (trem fye´ ah) (guselkumab) injection, for intravenous use

What is the most important information I should know about TREMFYA?

TREMFYA may cause serious side effects, including:

- **Serious allergic reactions.** Stop using TREMFYA and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - swelling of your face, eyelids, lips, mouth, tongue or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash, hives
  - itching
- **Infections.** TREMFYA is a medicine that may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA and may treat you for TB before you begin treatment with TREMFYA if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA.
  Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:
  - fever, sweats, or chills
  - cough
  - shortness of breath
  - blood in your phlegm (mucus)
  - muscle aches
  - warm, red, or painful skin or sores on your body different from your psoriasis
  - weight loss
  - diarrhea or stomach pain
  - burning when you urinate or urinating more often than normal

See **"What are the possible side effects of TREMFYA?"** for more information about side effects.

What is TREMFYA?

TREMFYA is a prescription medicine used to treat adults:

- with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light)
- with active psoriatic arthritis (PsA).
- with moderately to severely active ulcerative colitis

It is not known if TREMFYA is safe and effective in children under 18 years of age.

Do not use TREMFYA if you have had a serious allergic reaction to guselkumab or any of the other ingredients in TREMFYA. See the end of this Medication Guide for a complete list of ingredients in TREMFYA.

Before using TREMFYA, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **"What is the most important information I should know about TREMFYA?"**
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA.
- are pregnant or plan to become pregnant. It is not known if TREMFYA can harm your unborn baby.
  Pregnancy Registry: If you become pregnant during treatment with TREMFYA, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA. You can enroll in this registry by visiting www.mothertobaby.org/ongoing-study/tremfya-guselkumab, by calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu. The purpose of this registry is to collect information about the safety of TREMFYA during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use TREMFYA/TREMFYA PEN?

See the detailed "Instructions for Use" that comes with TREMFYA/TREMFYA PEN for information on how to prepare and inject a dose of TREMFYA, and how to properly throw away (dispose of) the used TREMFYA prefilled syringe, One-Press injector or prefilled pen (TREMFYA PEN).

- Use TREMFYA exactly as your healthcare provider tells you to use it.
- If you miss your TREMFYA dose, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Call your healthcare provider if you are not sure what to do.
- If you inject more TREMFYA than prescribed, call your healthcare provider right away.
- Adults with plaque psoriasis or psoriatic arthritis will receive TREMFYA as an injection under the skin (subcutaneous injection).
- Adults with ulcerative colitis will receive their starter doses with TREMFYA through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider. After completing the starter doses, patients will receive TREMFYA as an injection under the skin (subcutaneous injection).

What are the possible side effects of TREMFYA?

TREMFYA may cause serious side effects including:

- **See "What is the most important information I should know about TREMFYA?"**

The most common side effects of TREMFYA include:

- respiratory tract infections
- joint pain (arthralgia)
- fungal skin infections
- headache
- diarrhea
- herpes simplex infections
- injection site reactions
- stomach flu (gastroenteritis)
- bronchitis

These are not all the possible side effects of TREMFYA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TREMFYA?

- Store TREMFYA in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep TREMFYA in the original carton to protect it from light until time of use.
- TREMFYA is not made with natural rubber latex.
- Do not freeze TREMFYA.
- Do not shake TREMFYA.

Keep TREMFYA and all medicines out of the reach of children.

General information about the safe and effective use of TREMFYA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TREMFYA for a condition for which it was not prescribed. Do not give TREMFYA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about TREMFYA that is written for health professionals.

What are the ingredients in TREMFYA?

Active ingredient: guselkumab

Inactive ingredients: Single-dose prefilled syringe, single-dose One-Press patient-controlled injector, single-dose prefilled pen for subcutaneous use: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. Single-dose vial for intravenous infusion: EDTA disodium dihydrate, L-histidine, L-histidine monohydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA, U.S. License Number 1864
For patent information: www.janssenpatents.com

For more information, call 1-800-526-7736 or go to www.tremfya.com.

This Medication Guide had been approved by the U.S. Food and Drug Administration. Revised: 09/2024

Instructions for Use

TREMFYA® (trem fye´ ah) (guselkumab)

Prefilled Syringe

SINGLE-DOSE

Important

TREMFYA comes as a single-dose prefilled syringe containing one 100 mg dose. Each TREMFYA prefilled syringe can only be used one time. Throw the used prefilled syringe away (See Step 3) after one dose, even if there is medicine left in it. Do not reuse your TREMFYA prefilled syringe.

If your healthcare provider decides that you or a caregiver may be able to give your injections of TREMFYA at home, you should receive training on the right way to prepare and inject TREMFYA using the prefilled syringe before attempting to inject. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.

Read this Instructions for Use before using your TREMFYA prefilled syringe and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

The TREMFYA prefilled syringe is intended for injection under the skin, not into the muscle or vein. After injection, the needle will retract into the body of the device and lock into place.

Storage information

Store in refrigerator at **36° to 46°F** (2° to 8°C).

Do not freeze TREMFYA prefilled syringe.

Keep TREMFYA prefilled syringe and all medicines out of reach of children.

Do not shake your TREMFYA prefilled syringe.

Keep TREMFYA prefilled syringe in the original carton to protect from light and physical damage.

Prefilled syringe parts

Before use

Plunger
Do not hold or pull plunger at any time.

Safety guard

Finger flange

Body
Hold syringe body **below** finger flange.

Viewing window

Needle cover
Do not remove until you are ready to inject TREMFYA (See Step 2).

After use

Plunger locks

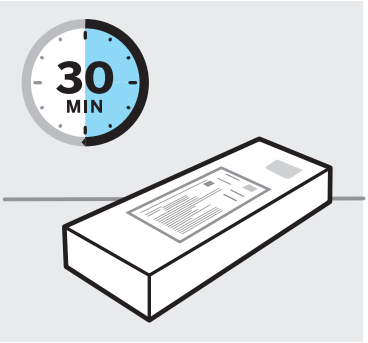
Safety guard activates

Needle retracts into the body

You will need these supplies:
- **1 TREMFYA prefilled syringe**

Not provided in the TREMFYA prefilled syringe carton:
- **1 Alcohol swab**
- **1 Cotton ball** or **gauze pad**
- **1 Adhesive bandage**
- **1 Sharps container** (See Step 3)

1. Prepare for your injection



Inspect carton

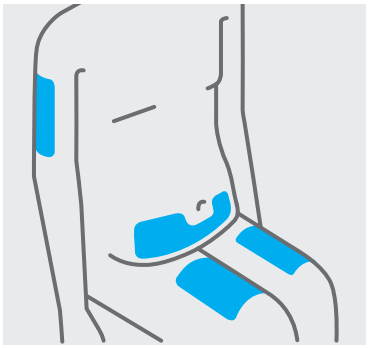
Remove your TREMFYA prefilled syringe carton from the refrigerator. Keep the prefilled syringe in the carton and let it sit on a flat surface at room temperature for **at least 30 minutes** before use.

Do not warm the prefilled syringe any other way.

Check the expiration date ('EXP') on the back panel of the carton.

Do not use your prefilled syringe if the expiration date has passed.

Do not inject TREMFYA if the perforations on the carton are broken. Call your healthcare provider or pharmacist for a refill.

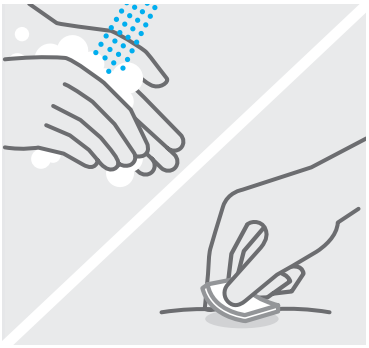


Choose injection site

Select from the following areas for your injection:

- **Front of thighs** (recommended)
- Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)
- Back of upper arms (only if someone else is giving you the injection)

Do not inject into skin that is tender, bruised, red, hard, thick, scaly or affected by psoriasis.

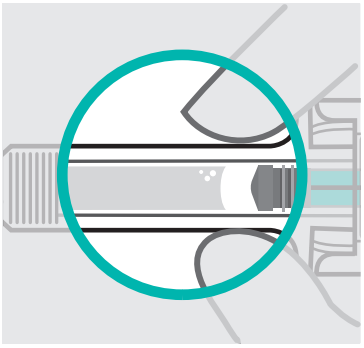


Clean injection site

Wash your hands well with soap and warm water.

Wipe your chosen injection site with an alcohol swab and allow it to dry.

Do not touch, fan, or blow on the injection site after you have cleaned it.



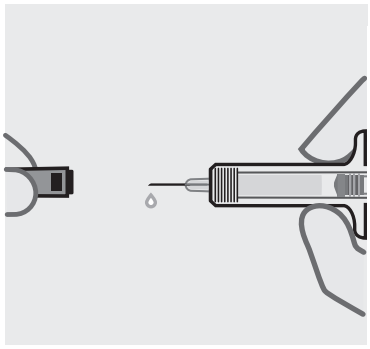
Inspect liquid

Take your TREMFYA prefilled syringe out of the carton.

Check the TREMFYA prefilled syringe liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles. This is normal.

Do not inject if the liquid is cloudy or discolored, or has large particles. Call your healthcare provider or pharmacist for a refill.

2. Inject TREMFYA using prefilled syringe



Remove needle cover

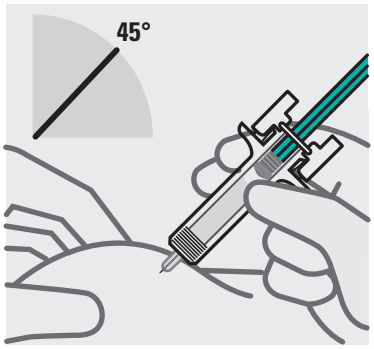
Hold your prefilled syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

Inject TREMFYA within 5 minutes of removing the needle cover.

Do not put needle cover back on, as this may damage the needle or cause a needle stick injury.

Do not touch needle or let it touch any surface.

Do not use a TREMFYA prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a refill.



Position fingers and insert needle

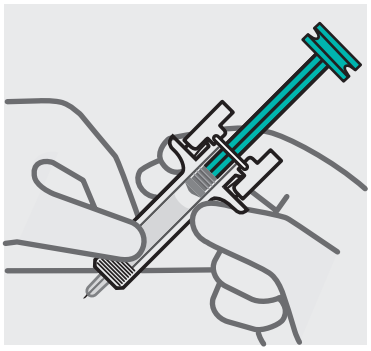
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.

Use your other hand to pinch skin at the injection site. Position syringe at about a 45 degree angle to the skin.

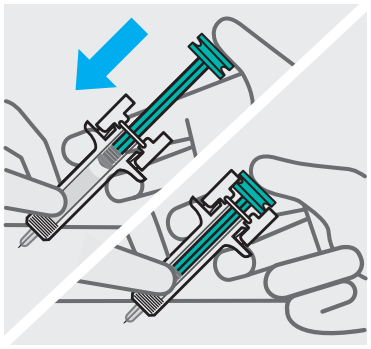
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



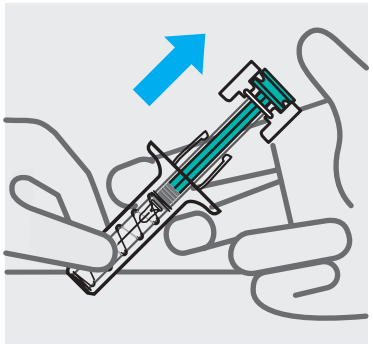
Release pinch and reposition hand

Use your free hand to grasp the body of the prefilled syringe.



Press plunger

Place thumb from the opposite hand on the plunger and press the plunger **all the way down until it stops.**



Release pressure from plunger

The safety guard will cover the needle and lock into place, removing the needle from your skin.

3. After your injection

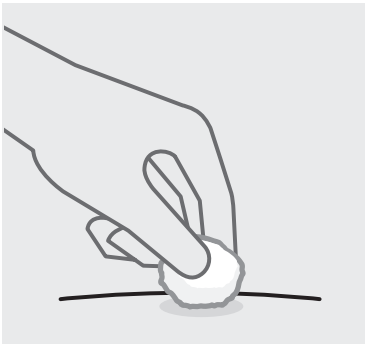
Dispose of your prefilled syringe

Put your used TREMFYA prefilled syringe in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your TREMFYA prefilled syringe in your household trash.

Do not recycle your used sharps disposal container.

For more information, see "How should I dispose of the used prefilled syringe?"



Check injection site

There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site.

If needed, cover injection site with a bandage.

Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback call 800-JANSSEN (800-526-7736).

How should I dispose of the used prefilled syringe?

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: www.fda.gov/safesharpsdisposal

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

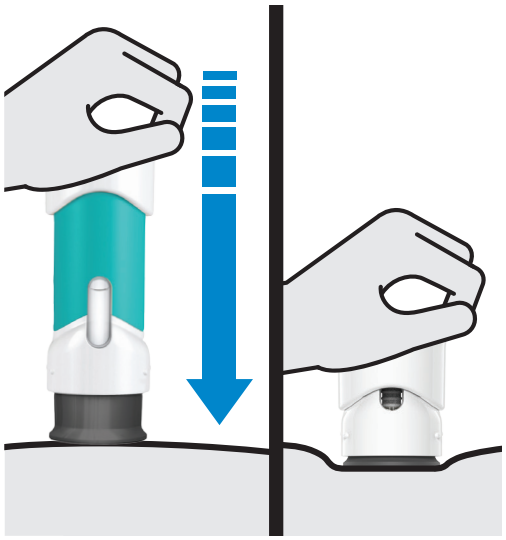
Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044
US License No. 1864

janssen

Approved: December 2017

INSTRUCTIONS FOR USE
TREMFYA® [trem fye' ah]
(guselkumab)
injection, for subcutaneous use
One-Press Patient-Controlled Injector

This "Instructions for Use" contains information on how to inject TREMFYA.



Important Information You Need to Know Before Injecting TREMFYA

TREMFYA comes in a single-dose One-Press injector containing one 100 mg dose.

During injection, push handle all the way down until teal body is not visible to inject the full dose.

DO NOT LIFT ONE-PRESS during injection. If you do, the One-Press will lock and you will not get the full dose.

Each One-Press injector can only be used one time. Throw away (See Step 3) after one dose, even if there is medicine left in it. Do not reuse your One-Press injector.

If your healthcare provider decides that you or a caregiver may be able to give your injections of TREMFYA at home, you should receive training on the right way to prepare and inject TREMFYA using the One-Press injector. Do not try to inject yourself until you have been trained by your healthcare provider.

Please read this Instructions for Use before using your One-Press injector and each time you get a new One-Press injector. There may be new information.

This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

Storage information

Store in refrigerator at **36° to 46°F** (2° to 8°C).

Do not freeze your One-Press injector.

Do not shake your One-Press injector.

Keep your One-Press injector and all medicines out of reach of children.

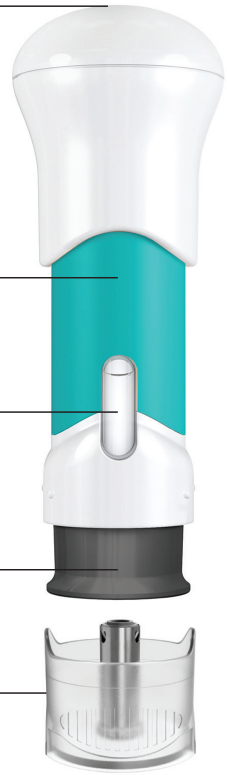
Keep your One-Press injector in the original carton to protect from light and physical damage.

Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback call 800-JANSSEN (800-526-7736).

One-Press injector parts

Before use



Handle

Teal Body

Window

Needle Guard

Bottom Cap
Remove cap before injecting (see Step 2).

After use

Handle is Pressed all the way down.

The teal body is not visible.

After lifting, the needle guard locks and the yellow band is visible.
Do not lift during the injection.

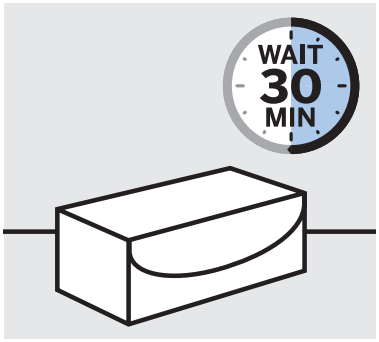
You will need:

- **1 One-Press injector**

Not provided in the carton:

- **1 Alcohol swab**
- **1 Cotton ball** or **gauze pad**
- **1 Adhesive bandage**
- **1 Sharps container** (See Step 3)

1. Preparing to Inject TREMFYA

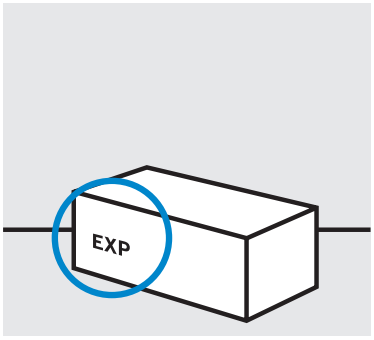


Inspect carton and allow TREMFYA to come to room temperature

Remove your One-Press injector carton from the refrigerator.

Keep your One-Press injector in the carton and let it sit on a flat surface at room temperature for **at least 30 minutes** before use.

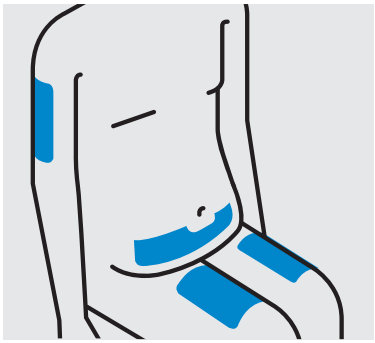
Do not warm your One-Press injector any other way.



Check the expiration date ('EXP') on the carton

Do not use your One-Press injector if the expiration date has passed.

Do not inject TREMFYA if the seal on the carton is broken. Call your healthcare provider or pharmacist for a new One-Press injector.



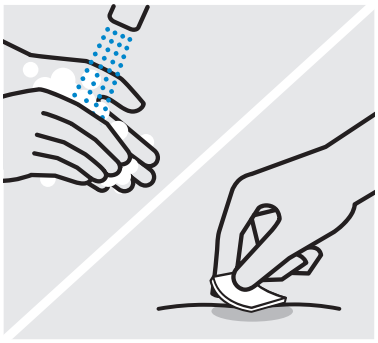
Choose injection site

Select from the following areas for your injection:

- **Front of thighs** (recommended)
- Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)
- Back of upper arms (only if someone else is giving you the injection)

Do not inject into skin that is tender, bruised, red, hard, thick, scaly, or affected by psoriasis.

1. Preparing to Inject TREMFYA (continued)



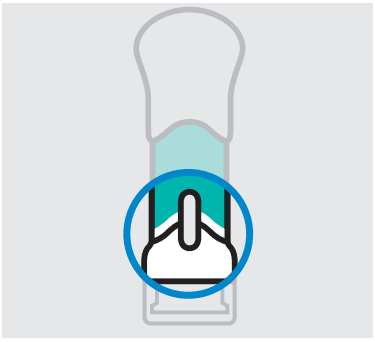
Wash hands

Wash your hands well with soap and warm water.

Clean injection site

Wipe your chosen injection site with an alcohol swab and allow it to dry.

Do not touch, fan, or blow on the injection site after you have cleaned it.



Inspect liquid in window

Take your One-Press injector out of the carton.

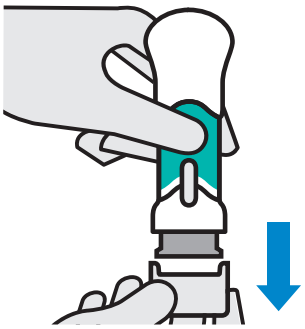
Check the liquid in the window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles. This is normal.

Do not inject if the liquid is:

- cloudy,
- discolored, or
- has large particles.

Call your healthcare provider or pharmacist for a new One-Press injector.

2. Injecting TREMFYA



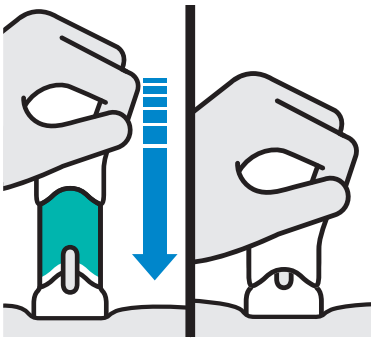
Pull off bottom cap

Keep hands away from the needle guard after the cap is removed. It is normal to see a few drops of liquid.

Inject TREMFYA within 5 minutes of removing the cap.

Do not put the cap back on. This could damage the needle.

Do not use a One-Press injector if it is dropped after removing the cap. Call your healthcare provider or pharmacist for a new One-Press injector.



Place straight on skin.

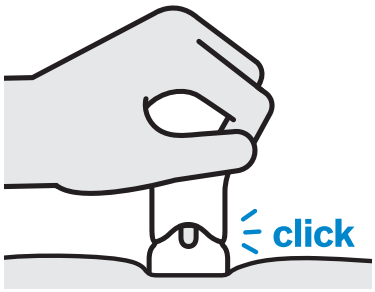
Push handle all the way down until teal body is not visible

DO NOT LIFT ONE-PRESS during injection!
If you do, the needle guard will lock, showing a yellow band, and you will not get the full dose.

You may hear a click when the injection begins. Keep pushing.

If you feel resistance, keep pushing. This is normal.

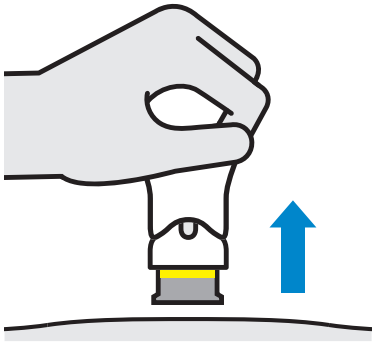
The medication injects as you push. Do this at a speed that is comfortable for you.



Confirm your injection is complete

Your injection is complete when:

- **The teal body is not visible.**
- You cannot press the handle down anymore.
- You may hear a click.



Lift straight up

The yellow band indicates that the needle guard is locked.

3. After your injection

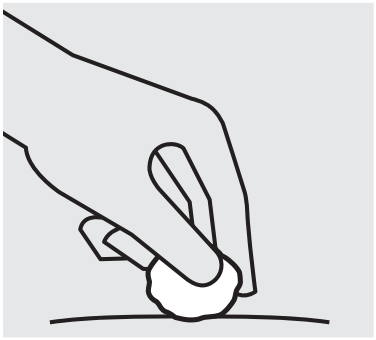
Dispose of your One-Press injector

Put your used One-Press injector in a sharps disposal container right away after use.

Do not throw away (dispose of) your One-Press injector in your household trash.

Do not recycle your used sharps disposal container.

For more information, see "Disposing of TREMFYA One-Press injector".



Check injection site

There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site.

If needed, cover injection site with a bandage.

Disposing of TREMFYA One-Press injector

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: www.fda.gov/safesharpsdisposal. You may also consult your pharmacist.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044
US License No. 1864

Revised: June 2023

janssen

Instructions for Use

TREMFYA® (trem fye´ ah) (guselkumab)

injection, for subcutaneous use

200mg/2mL Prefilled Syringe

SINGLE-DOSE

This Instructions for Use contains information on how to inject TREMFYA.

Important Information You Need to Know Before Injecting TREMFYA

TREMFYA comes in a single-dose prefilled syringe containing one 200 mg dose.

If your healthcare provider decides that you or a caregiver may be able to give your injections of TREMFYA at home, you should receive training on the correct way to prepare and inject TREMFYA before using the prefilled syringe.

Read this Instructions for Use before using your TREMFYA prefilled syringe and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

Each TREMFYA prefilled syringe can only be used one time. Throw the used prefilled syringe away (see Step 4) after one dose, even if there is still medicine left in it. Do not reuse your TREMFYA prefilled syringe.

The TREMFYA prefilled syringe is intended for injection under the skin, not into the muscle or vein. After injection, the needle will retract into the device and lock into place.

Storage information

Store in refrigerator between **36°F to 46°F** (2°C to 8°C).

Do not freeze TREMFYA prefilled syringe.

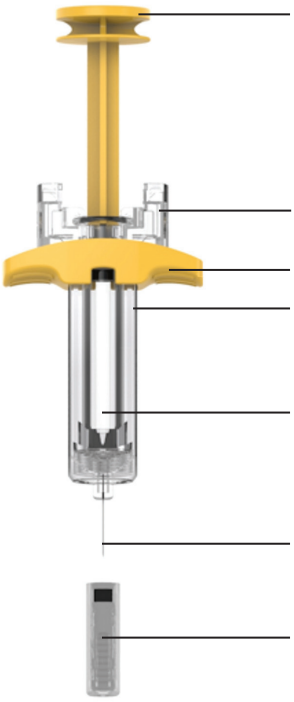
Do not shake your TREMFYA prefilled syringe.

Keep TREMFYA prefilled syringe and all medicines out of reach of children.

Keep TREMFYA prefilled syringe in the original carton to protect from light and physical damage.

Prefilled syringe parts

Before use



Plunger
Do not hold or pull plunger at any time.

Safety guard

Finger flange

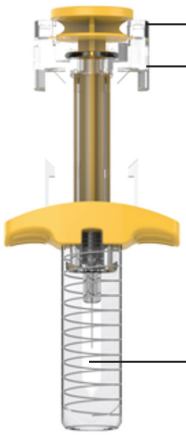
Body

Viewing window

Needle

Needle cover
Do not remove until you are ready to inject (See Step 3).

After use



Plunger locks

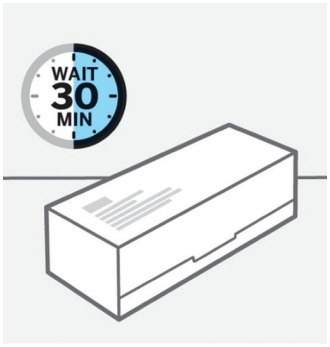
Safety guard activates

Needle retracts into the body

You will need:
- **1 prefilled syringe**

Not provided in the carton:
- **Alcohol swabs**
- **Cotton balls** or **gauze pads**
- **Adhesive bandages**
- **Sharps container** (See Step 4)

1. Get ready



Allow TREMFYA to come to room temperature and inspect carton

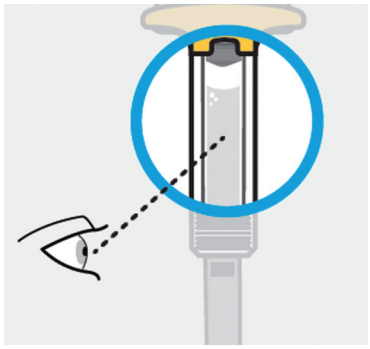
Remove the carton from the refrigerator and let the carton sit on a flat surface at room temperature for approximately **30 minutes** before use.

Do not warm the prefilled syringe any other way.

Check the expiration ('EXP') date.

Do not use your prefilled syringe if the expiration date has passed or if the seal on the carton is broken. Contact your healthcare provider or pharmacist for a new prefilled syringe.

2. Prepare to inject TREMFYA



Take the prefilled syringe out of the carton.

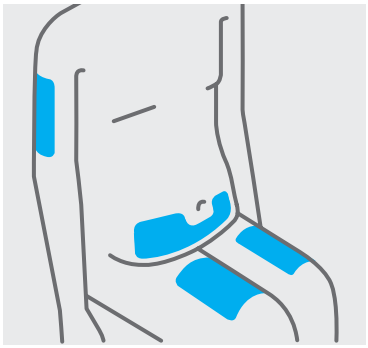
Inspect liquid to see that it is clear and colorless to slightly yellow

Check the liquid in the viewing window. It should be clear and colorless to slightly yellow and may contain tiny white or clear particles. You may also see air bubbles. This is normal.

Do not inject if the liquid is:

- cloudy or
- discolored or
- has large particles

Do not use the prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a new prefilled syringe.

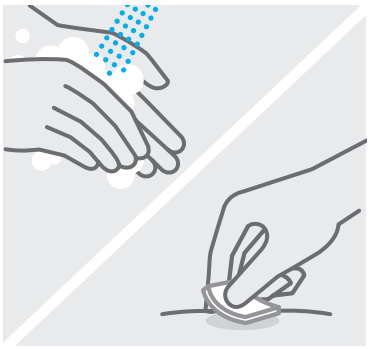


Choose injection site

Select from the following areas for your injection:

- Front of thighs
- Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)
- Back of upper arms (only if someone else is giving you the injection)

Do not inject into skin that is tender, bruised, red, scaly, thick or hard. Avoid areas with scars or stretch marks.



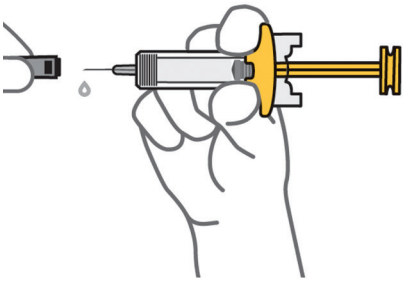
Wash hands and clean injection site

Wash your hands well with soap and warm water.

Wipe your chosen injection site with an alcohol swab and allow it to dry.

Do not touch, fan, or blow on the injection site after you have cleaned it.

3. Inject TREMFYA



Remove needle cover when you are ready to inject

Hold the prefilled syringe by the body and pull needle cover straight off. It is normal to see a few drops of liquid.

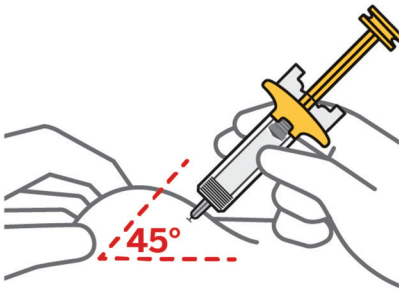
Inject TREMFYA within 5 minutes of removing the needle cover.

Do not put needle cover back on, as this may damage the needle or cause a needle stick injury.

Do not touch needle or let it touch any surface.

Do not use the prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a new prefilled syringe.

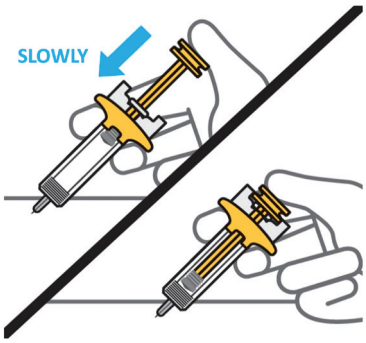
Do not hold or pull the plunger at any time.



Pinch injection site and insert needle at about a 45-degree angle

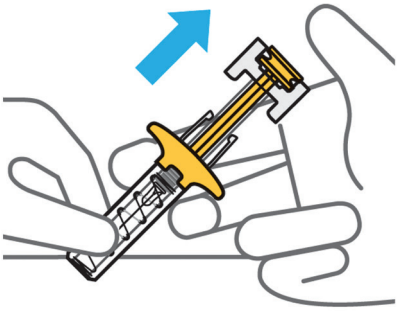
It is important to pinch enough skin to inject under the skin and not into muscle.

Insert needle with a quick dart-like motion.



Slowly press plunger all the way down until it stops to inject all of the liquid

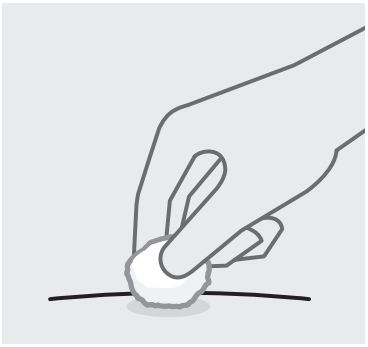
You will feel some resistance as you press the plunger, this is normal.



Release pressure from plunger to remove the needle from the skin

The needle will retract into the device and lock into place.

4. After your injection

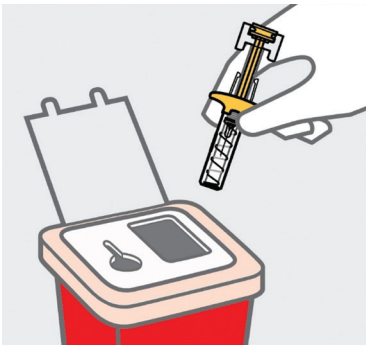


Check injection site

There may be a small amount of blood or liquid at the injection site. Gently hold pressure over the injection site with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site.

If needed, cover the injection site with a bandage.



Dispose of your prefilled syringe

Put the used prefilled syringe in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your prefilled syringe in your household trash.

Do not recycle your used sharps disposal container.

For more information, see Disposing of TREMFYA prefilled syringe.

Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback, call 800-526-7736.

Disposing of TREMFYA prefilled syringe

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic
- can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: www.fda.gov/safesharpsdisposal. You may also consult your pharmacist.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

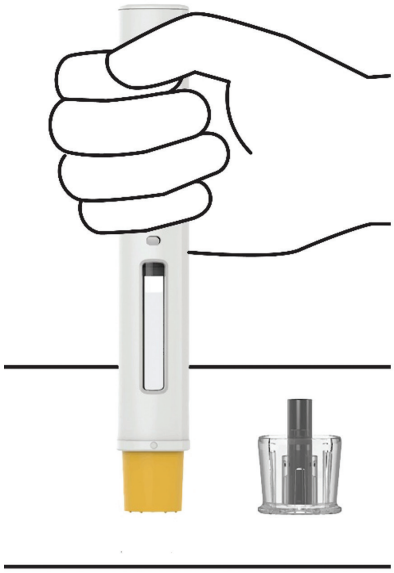
Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044, USA
US License No. 1864

Janssen

Approved: September 2024

INSTRUCTIONS FOR USE
TREMFYA® PEN [trem fye' ah Pen]
(guselkumab)
injection, for subcutaneous use
200mg/2mL Prefilled Pen

This Instructions for Use contains information on how to inject TREMFYA PEN.



SINGLE-DOSE

Important Information You Need to Know Before Injecting TREMFYA PEN

TREMFYA PEN comes in a single-dose Prefilled Pen containing one 200 mg dose.

If your healthcare provider decides that you or a caregiver may be able to give your injections of TREMFYA PEN at home, you should receive training on the correct way to prepare and inject TREMFYA PEN before using the Prefilled Pen.

Read this Instructions for Use before using your Prefilled Pen and each time you get a new Prefilled Pen. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

Each TREMFYA PEN can only be used one time. Throw the used Prefilled Pen away (see Step 4) after one dose, even if there is still medicine left in it. Do not reuse your Prefilled Pen.

Storage information

Store in refrigerator between **36° to 46°F** (2° to 8°C).

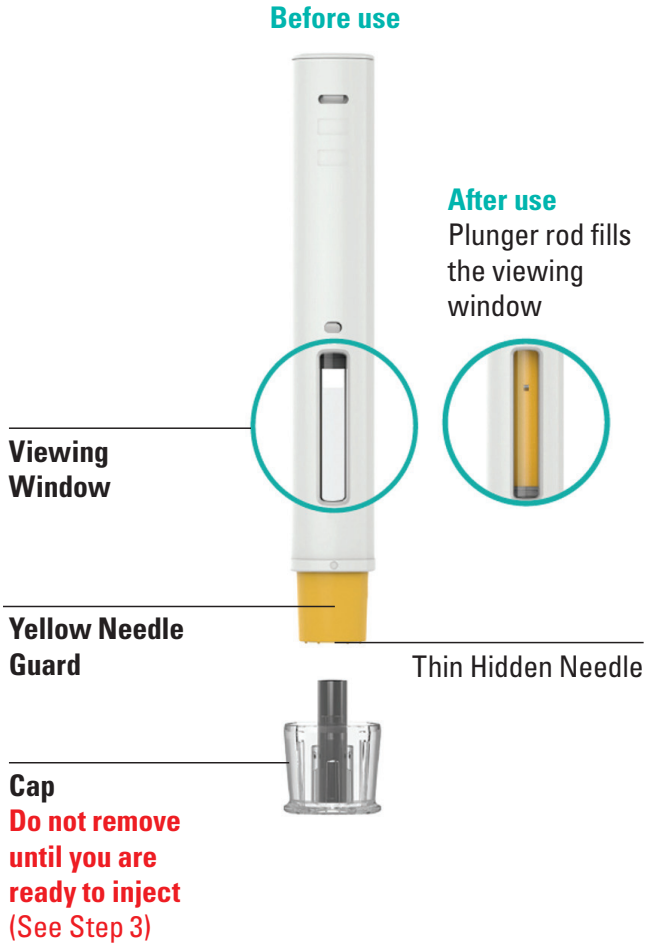
Do not freeze your TREMFYA PEN.

Do not shake your TREMFYA PEN.

Keep your TREMFYA PEN and all medicines out of reach of children.

Keep your TREMFYA PEN in the original carton to protect from light and physical damage.

TREMFYA PEN parts



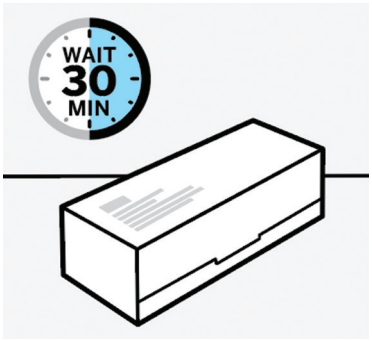
You will need:

- **1 Prefilled Pen**

Not provided in the carton:

- **Alcohol swabs**
- **Cotton balls** or **gauze pads**
- **Adhesive bandages**
- **Sharps container** (See Step 4)

1. Get ready



Allow TREMFYA PEN to come to room temperature and inspect carton

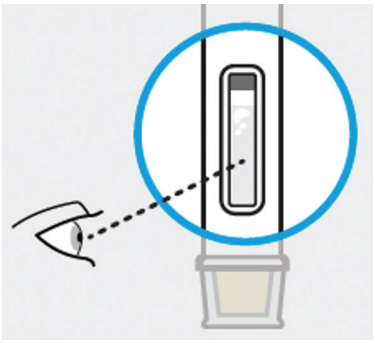
Remove the carton from the refrigerator and let the carton sit on a flat surface at room temperature for approximately **30 minutes** before use.

Do not warm the Prefilled Pen any other way.

Check the expiration ('EXP') date.

Do not use the Prefilled Pen if the expiration date has passed or if the seal on the carton is broken. Contact your healthcare provider or pharmacist for a new Prefilled Pen.

2. Prepare to Inject TREMFYA PEN



Take your Prefilled Pen out of the carton.

Inspect liquid in window to see that it is clear and colorless to slightly yellow

Check the liquid in the viewing window. It should be clear and colorless to slightly yellow and may contain tiny white or clear particles. You may also see air bubbles. This is normal.

Do not inject if the liquid is:

- cloudy or
- discolored or
- has large particles

Call your healthcare provider or pharmacist for a new Prefilled Pen.

Choose injection site

Select from the following areas for your injection:

- Front of thighs
- Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)
- Back of upper arms (only if someone else is giving you the injection)

Do not inject into skin that is tender, bruised, red, scaly, thick or hard. Avoid areas with scars or stretch marks.

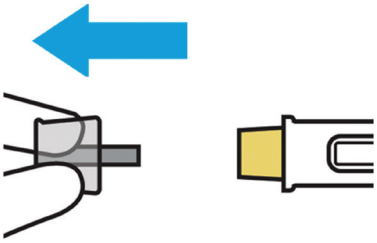
Wash hands and clean injection site

Wash your hands well with soap and warm water.

Wipe your chosen injection site with an alcohol swab and allow it to dry.

Do not touch, fan, or blow on the injection site after you have cleaned it.

3. Inject TREMFYA PEN



Remove cap when you are ready to inject

Do Not Touch Yellow Needle Guard!
This may start the injection and you will not receive the dose.

Pull the cap straight off. It is normal to see a few drops of liquid.

Inject TREMFYA PEN within 5 minutes of removing cap.

Do not put the cap back on as this may damage the needle.

Do not use your Prefilled Pen if it is dropped after removing the cap. Call your healthcare provider or pharmacist for a new Prefilled Pen.

Position the Prefilled Pen straight onto the injection site then push and hold the Prefilled Pen

Do Not Lift The Prefilled Pen During Injection!
If you do, the yellow needle guard will lock and the full dose will not be delivered.

Position your Prefilled Pen straight onto the injection site with the yellow needle guard against the skin and the viewing window facing you.

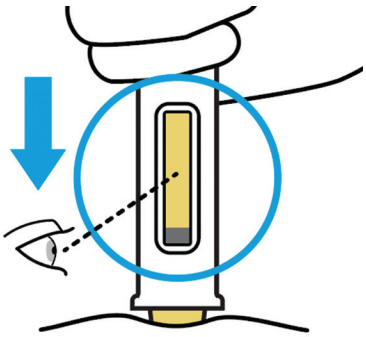
Press down on the Prefilled Pen and keep holding it down against the skin.

You will hear the first click.

Keep holding your Prefilled Pen firmly against the skin for about 10 seconds to hear a second click

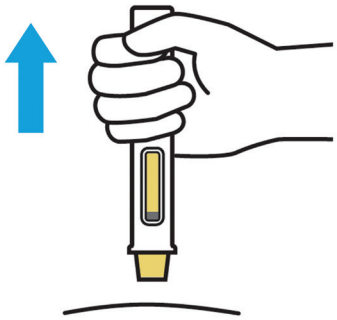
You are almost done.

3. Inject TREMFYA PEN (continued)



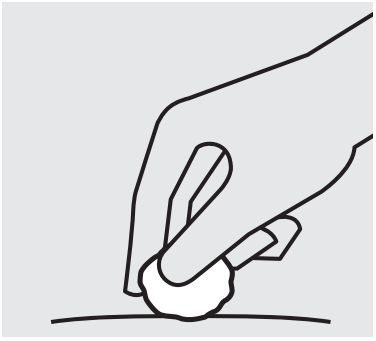
Keep holding firmly against the skin and confirm your injection is complete

Your injection is complete when the plunger rod stops moving and fills the viewing window.



Lift straight up

4. After your injection



Check injection site

There may be a small amount of blood or liquid at the injection site. Gently hold pressure over the injection site with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site. If needed, cover the injection site with a bandage.

Dispose of your Prefilled Pen and cap

Put your used Prefilled Pen and cap in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your Prefilled Pen in your household trash.

Do not recycle your used sharps disposal container.

For more information, see Disposing of TREMFYA PEN.

Disposing of TREMFYA PEN

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic
- can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: www.fda.gov/safesharpsdisposal. You may also consult your pharmacist.

Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback, call 800-526-7736.

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