PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **STELARA**®
'stel ar' a'
ustekinumab injection
Solution for Subcutaneous Injection

Read this carefully before you start taking **Stelara** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Stelara**.

What is Stelara used for?

- **Adults with Plaque Psoriasis**

Stelara is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

- **Children 6 to 17 years of age with Plaque Psoriasis**

Stelara is a prescription medicine that is approved for children and adolescent patients 6 to 17 years of age with moderate to severe plaque psoriasis that is chronic (doesn't go away) and who have had an inadequate response to other treatments.

- **Adults with Psoriatic Arthritis**

Stelara is a prescription medicine that is approved for adults with active psoriatic arthritis.

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given Stelara by injection under the skin, alone or in combination with methotrexate, to reduce signs and symptoms of your arthritis, help improve your ability to perform daily activities (such as dressing, walking and climbing stairs) and improve your psoriasis.

- **Adults with Crohn's disease or ulcerative colitis**

Stelara/Stelara I.V. is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease and for adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, Stelara I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of Stelara are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given Stelara/Stelara I.V. to help relieve your symptoms and keep the disease under control. Stelara/Stelara I.V. may help reduce or stop the use of your corticosteroid medication.

How does Stelara work?

Stelara blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

What are the ingredients in Stelara?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. No preservatives are present.

Stelara comes in the following dosage forms:

Pre-filled Syringe:

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:

- 45 mg / 0.5 mL

Do not use Stelara if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to Stelara, Stelara I.V., or any of the other ingredients in Stelara. See below for a complete list of ingredients in Stelara.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine while taking Stelara.

If you used Stelara while pregnant, tell your baby's healthcare professional about your Stelara use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

Always keep medicine out of the reach of children.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Stelara. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Stelara or Stelara I.V. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received “allergy shots”, especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. Stelara may pass into your breast milk in small amounts.

Contact your healthcare professional immediately:

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

The needle cover on the pre-filled syringe contains dry natural rubber (a form of latex). This may cause allergic reactions in people who are sensitive to latex. Tell your healthcare professional if you have ever had an allergic reaction to latex and developed any allergic reaction to Stelara injection.

There is limited experience with Stelara in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Stelara and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use Stelara.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

The following may interact with Stelara:

- Stelara may change the way the body responds to live vaccines.
- Stelara may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your health care provider.

How to take Stelara:

<u>Instructions for injecting Stelara under the skin yourself</u>:

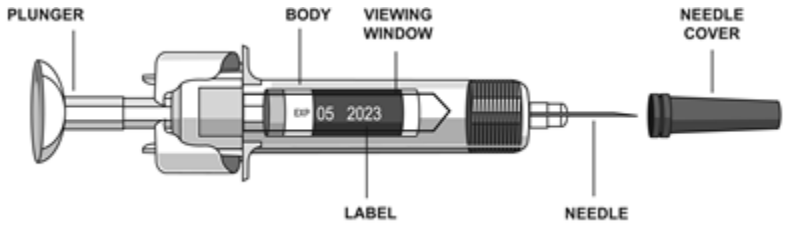
Stelara may be injected by your healthcare provider. In children 6 to 17 years of age, it is recommended that all doses of Stelara be administered by a health care provider. However, your healthcare professional may decide that it is right for you or your caregiver to learn how to inject Stelara under the skin (subcutaneously) yourself. Before you self-inject Stelara, you must be trained by a healthcare professional. If you or your caregiver have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection. Stelara is not to be mixed with other liquids for injection.

INSTRUCTIONS FOR INJECTING STELARA USING A PRE-FILLED SYRINGE

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

Do not shake Stelara at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

1: PREPARING FOR PRE-FILLED SYRINGE USE



Take the Syringe out of the Refrigerator
If your dose amount is 90 mg and you receive two 45 mg packages, you need to give a second injection right after the first. Choose a different site for the second injection. Children who weigh 60 kg or more may use the prefilled syringe.

Check Expiration Date
Open the box and remove the pre-filled syringe. Check the expiration date on the pre-filled syringe and the label of the box. If the expiration date has passed, or if the pre-filled syringe has been kept at room temperature up to 30°C for longer than 30 days or if the pre-filled syringe has been stored above 30°C, DO NOT use the pre-filled syringe.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.

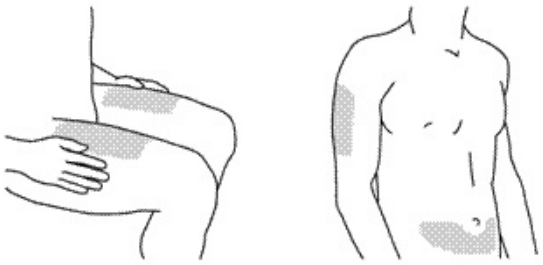
Check Solution in Syringe
Hold the pre-filled syringe with the covered needle pointing upward. Make sure the syringe is not damaged. Look at the solution or liquid in the syringe to make sure that it is clear to slightly opalescent and colourless to slightly yellow. DO NOT use if it is frozen, discoloured, cloudy or contains particles and contact your healthcare provider for assistance.

DO NOT remove the needle cover from the pre-filled syringe.

DO NOT pull back on the plunger head at any time.

2: CHOOSING AND PREPARING THE INJECTION SITE

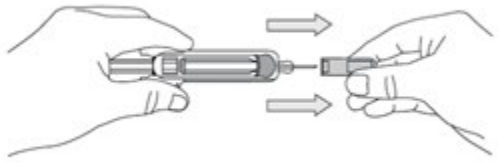
Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.



*Areas in gray are recommended injection sites.

Prepare the Injection Site
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: INJECTING THE MEDICATION



Remove the Needle Cover
When you are ready to inject, pick up the pre-filled syringe, hold the body of the syringe with one hand and pull the needle cover straight off. Throw the needle cover into the trash. You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal. Do not touch the needle or allow it to touch any surface.

Note: The needle cover should NOT be removed until you are ready to inject the dose. Do not use syringe if it is dropped without the needle cover in place. If you drop the syringe without the needle cover in place, please contact your healthcare provider for assistance.

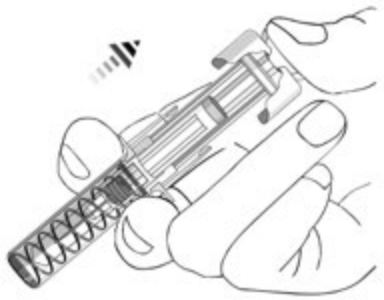
Inject the Medication
Gently pinch the cleaned skin between your thumb and index finger. Don’t squeeze it.

Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid.

Push it slowly and evenly, keeping the skin pinched.

When the plunger meets the end of the syringe barrel, and all of the medication has been injected, release the pinched skin and gently remove the needle. Following complete injection, the needle guard will automatically extend over the needle and lock as you take your hand off the plunger.



4: AFTER THE INJECTION

Dispose of the Empty Syringe
Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, needles and syringes **must NEVER** be re-used. Dispose of sharps container according to your local regulations.

Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

INSTRUCTIONS FOR INJECTING STELARA FROM A 45 mg/0.5 mL VIAL

Do not shake Stelara Solution for Subcutaneous Injection at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it. Stelara is not to be mixed with other liquids for injection.

1: CHECK VIAL(S) AND ASSEMBLE MATERIALS

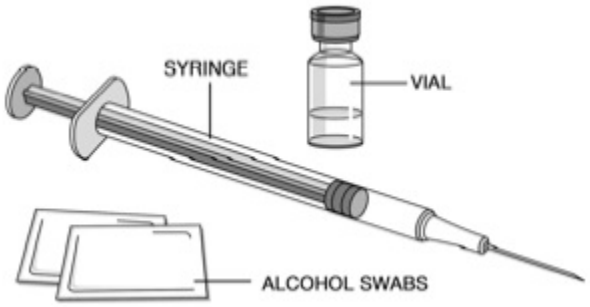
Take the Vial(s) out of the Refrigerator
If your dose is 45 mg you will receive one 45 mg vial. If your dose is 90 mg, you will receive two 45 mg vials. If you receive two 45 mg vials for a 90 mg dose, you will need to give yourself two injections one right after the other. Use a new needle and syringe. Choose a different site for the second injection.

Children weighing less than 60 kg require a dose lower than 45 mg. Make sure you know the proper amount (volume) and type of syringe needed for dosing. If you don't know the amount or type of syringe needed, contact your healthcare provider for further instructions.

Check Expiration Date
Open the box and remove the vial. Check the expiration date on the vial and the label of the box. If the expiration date has passed, don't use it.

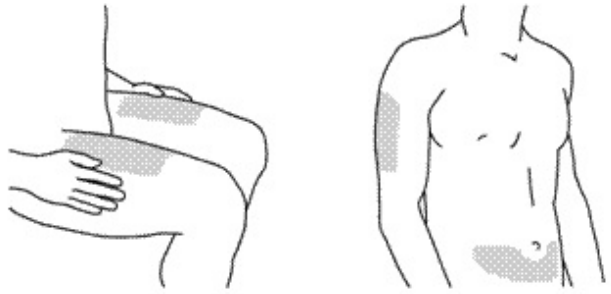
Check Solution in Vial
Make sure the vial is not damaged. Look at the solution or liquid in the vial to make sure that it is clear to slightly opalescent and colourless to slightly yellow. **DO NOT** use if it is frozen, discoloured, cloudy or contains particles and contact your healthcare provider for assistance.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.



2: CHOOSING AND PREPARING THE INJECTION SITE

Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.

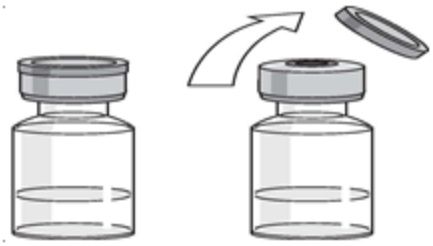


*Areas in gray are recommended injection sites.

Prepare the Injection site
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: PREPARING THE DOSE

Remove the cap from the top of the vial but do not remove the stopper. Clean the stopper with an antiseptic wipe.

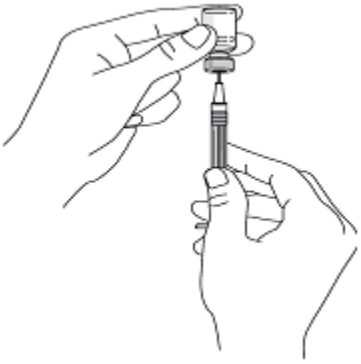


Remove the needle cover from the syringe. Do not touch the needle or allow the needle to touch anything.

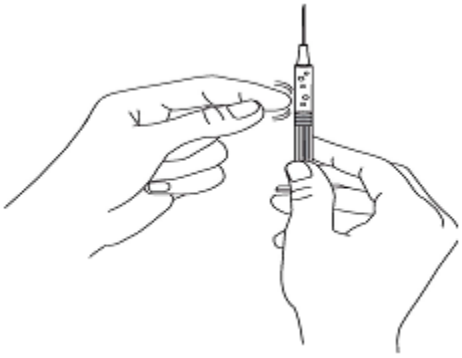
Put the vial on a flat surface and push the syringe needle through the rubber stopper.

Turn the vial and the syringe upside down.
For adults and children 6 to 17 years of age, who weigh 60 kg or more, pull on the syringe plunger to fill the syringe with the entire amount (volume) of liquid prescribed by your healthcare provider. It is important that the needle is always in the liquid in order to prevent air bubbles from forming in the syringe.

For children 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your health care provider may be less than 0.5 mL. Your health care provider will recommend how much liquid is needed.



Remove the needle from the vial
Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.



4: INJECTING THE MEDICATION

Gently pinch the cleaned skin between your thumb and index finger. Don’t squeeze it.

Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.

When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

Press an antiseptic wipe over the injection site for a few seconds after the injection.

Dispose the Empty Syringe and Vial(s)
Discard any unused portion of Stelara in accordance with local requirements. Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, vials, needles and syringes must NEVER be re-used. Dispose of sharps container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash.

Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

Usual dose:

Psoriasis
For treatment of psoriasis, Stelara is given by injection under the skin.

Adults:
The recommended dose of Stelara is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your healthcare professional may consider treating you as often as every 8 weeks.

90 mg may be used in patients with a body weight greater than 100 kg.

Pediatric Psoriasis (6 years of age or older):
The recommended dose of Stelara based on body weight (as shown below) is given at Week 0 and 4, and then every 12 weeks thereafter.

Weight	Recommended dose of Stelara	Dosage Form
< 60kg	0.75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Pre-filled syringe, vial
> 100 kg	90 mg	Pre-filled syringe

* For patients with body weight < 60 kg, use the vial presentation only. To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: body weight (kg) x 0.0083 (mL/kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. The calculated volume of injection per kg body weight at time of dosing are also provided in table below. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

Injection volumes of Stelara for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	**Dose (mg)**	**Volume of injection (mL)**
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

In children 6 to 17 of age with psoriasis, it is recommended that Stelara be administered by a health care provider. If your healthcare professional determines that it is appropriate, your caregiver or you may be able to administer Stelara to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the "**Instructions for injecting Stelara under the skin yourself**".)

Psoriatic Arthritis
For treatment of psoriatic arthritis, Stelara is given by injection under the skin. The recommended dose of Stelara is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

Crohn's disease and ulcerative colitis
For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of Stelara I.V. based on body weight (as shown below) followed by 90 mg Stelara given by injection under the skin (subcutaneous).

Weight	Recommended Dose of Stelara I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Stelara I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Stelara)
Further treatment	Every 8 weeks* Subcutaneous injection (Stelara)

* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The BioAdvance® Network has been established to facilitate the administration of Stelara. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of Stelara. Contact your healthcare professional if you have any questions.

Overdose:

Call your healthcare professional if you accidentally inject Stelara more frequently than instructed.

If you think you, or a person you are caring for, have taken too much Stelara, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose, contact your healthcare provider for guidance.

What are possible side effects from using Stelara?

These are not all the possible side effects you may have when taking Stelara. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of Stelara are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

Stelara is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- Stelara may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Stelara. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Stelara and during treatment with Stelara.

Cancers

- Stelara may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Stelara treatment.

Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	✓		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
UNCOMMON (≥0.1% and <1%)			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

In general, the side effects of Stelara seen in children 6 to 17 years of age are similar to those in adults.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

If you are using Stelara at home, it is important to store the product in your refrigerator at 2-8°C although not in the freezer compartment. Stelara should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake.

If needed, individual Stelara pre-filled syringes may also be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

Always keep medicine out of the reach and sight of children.

If you want more information about Stelara:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html, the manufacturer's website www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

Last revised: August 2024

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr STELARA® I.V.
'stel ar' a'
ustekinumab for injection
Solution for Intravenous Infusion

Read this carefully before you start taking **Stelara I.V.** This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Stelara I.V.**

What is Stelara I.V. used for?

- **Adults with Crohn's disease or ulcerative colitis**

Stelara I.V./Stelara is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease or adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, Stelara I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of Stelara are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given Stelara I.V./Stelara to help relieve your symptoms and keep the disease under control. Stelara I.V./ Stelara may help reduce or stop the use of your corticosteroid medication.

How does Stelara I.V. work?

Stelara I.V. blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with Crohn's disease and ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the digestive tract.

What are the ingredients in Stelara I.V.?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: EDTA disodium salt dihydrate, L-histidine and L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80 and sucrose. No preservatives are present.

Stelara I.V. comes in the following dosage forms:

Stelara I.V. is available as a sterile solution in single-use vials. Each vial contains 130 mg ustekinumab in 26 mL.

Do not use Stelara I.V. if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to Stelara I.V. or Stelara or any of the other ingredients in Stelara I.V. See below for a complete list of ingredients in Stelara I.V.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

<u>You should not receive a live vaccine when taking Stelara I.V.</u>

If you used Stelara I.V. while pregnant, tell your baby's healthcare professional about your Stelara I.V. use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Stelara I.V. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Stelara I.V. or Stelara. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received "allergy shots", especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. Stelara I.V. may pass into your breast milk in small amounts.

<u>Contact your healthcare professional immediately:</u>

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

There is limited experience with Stelara I.V./Stelara in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Stelara I.V. and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use Stelara I.V./Stelara.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

The following may interact with Stelara I.V.:

- Stelara I.V. may change the way the body responds to live vaccines.
- Stelara I.V. may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your health care provider.

How to take Stelara I.V.:

Usual dose:

Crohn's disease and ulcerative colitis
For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of Stelara I.V. based on body weight (as shown below) followed by 90 mg Stelara given by injection under the skin (subcutaneous).

Weight	Recommended Dose of Stelara I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Stelara I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Stelara)
Further treatment	Every 8 weeks* Subcutaneous injection (Stelara)

* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The initial dose of Stelara I.V. for intravenous infusion for Crohn's disease or ulcerative colitis will be given over a period of at least one hour.

The BioAdvance® Network has been established to facilitate the administration of Stelara I.V. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of Stelara I.V. infusions. Contact your healthcare professional if you have any questions.

Overdose:

In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse effects and appropriate symptomatic treatment be instituted immediately.

If you think you, or a person you are caring for, have taken too much Stelara I.V., contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Stelara I.V.?

These are not all the possible side effects you may have when taking Stelara. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of Stelara I.V. are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

Stelara I.V. is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- Stelara I.V. may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Stelara I.V. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Stelara I.V.

Cancers

- Stelara I.V. may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Stelara I.V. treatment.

Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	✓		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
UNCOMMON (≥0.1% and <1%)			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Stelara I.V. must be stored in the original package in the refrigerator at 2-8°C (36-46°F) before use. Stelara I.V. should not be frozen. Keep the product in its original carton to protect from light until the time of use. Do not shake. It must be kept out of the reach and sight of children.

If you want more information about Stelara I.V.:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html, the manufacturer's website www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

Last revised: August 2024