

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrRYBREVANT®

amivantamab for injection

50 mg/mL Concentrate for Solution for Infusion

Read this carefully before you start taking **Rybrevant**. 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 **Rybrevant**.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

What is Rybrevant used for?

- See the following boxed text

Rybrevant is used in adults with a type of cancer called 'non-small cell lung cancer'. It is used when the cancer has spread in your body and has gone through certain genetic changes (EGFR Exon 19 deletions, Exon 21 L858R substitution mutations, or Exon 20 insertion mutations) in a gene called 'epidermal growth factor receptor' (EGFR).

For the following indication, Rybrevant has been approved **with conditions (NOC/c)**. This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to verify Rybrevant's clinical benefit. For more information, talk to your healthcare professional.

Rybrevant can be prescribed for you:

- after chemotherapy stops working against your cancer.

For the following indications, Rybrevant has been approved **without conditions**. This means it has passed Health Canada's review and can be bought and sold in Canada.

Rybrevant can be prescribed for you:

- in combination with chemotherapy after osimertinib stops working against your cancer.
- as the first medicine you receive for your cancer in combination with chemotherapy.

How does Rybrevant work?

Amivantamab is an antibody, that is a type of protein, that has been designed to recognise and attach to specific targets in the body. Amivantamab targets two proteins found on cancer cells:

- Epidermal growth factor receptor (EGFR), and
- Mesenchymal-epithelial transition factor (MET).

Rybrevant works by attaching to these proteins. This may help to slow or stop your lung cancer from growing. It may also help to reduce the size of the tumour.

Rybrevant may be given in combination with other anti-cancer medicines. It is important that you also read the package leaflets for these other medicines. If you have any questions about these medicines, ask your doctor.

What are the ingredients in Rybrevant?

Medicinal ingredients: Amivantamab

Non-medicinal ingredients: Ethylenediaminetetraacetic acid (EDTA), L-histidine, L-methionine, polysorbate 80, sucrose, and water for injection

Rybrevant comes in the following dosage forms:

Liquid concentrate for intravenous infusion, 350 mg / 7 mL vial

Do not use Rybrevant if:

- you are allergic to amivantamab or any other ingredients of Rybrevant (see “**What are the ingredients in Rybrevant?**”)

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

- have a history of lung or breathing problems
- have suffered from inflammation of your lungs (a condition called “interstitial lung disease” or “pneumonitis”)

Other warnings you should know about:

Infusion related reactions: Before each infusion of Rybrevant, you will be given medicines which help to lower the chance of infusion related reactions. These may include:

- Medicines for an allergic reaction (antihistamines)
- Medicines for inflammation (corticosteroids)
- Medicines for fever (such as acetaminophen)

You may also be given additional medicines based on any symptoms you may experience. If

you have any further questions on the use of this medicine, ask your doctor or nurse.

Tell your doctor or nurse straight away while taking Rybrevant if you get any of the following side effects:

- Any side effect during the intravenous infusion (drip into a vein) of Rybrevant.
- Sudden difficulty in breathing (shortness of breath), cough, or fever that may suggest inflammation of the lungs.
- Skin and nail problems. To reduce the risk of skin problems, keep out of the sun, wear protective clothing, apply sunscreen, and use moisturisers regularly on your skin and nails while taking Rybrevant. You also need to do this for 2 months after you stop treatment.
- Eye problems. If you have vision problems or eye pain contact your doctor or nurse straight away. If you use contact lenses and have any new eye symptoms, stop using contact lenses and tell your doctor straight away.

Children and adolescents

Rybrevant should not be given to children or young people below 18 years of age. This is because it is not known how the medicine will affect them.

Contraception

If you or your partner could become pregnant, you must use effective contraception during and for 3 months after stopping treatment with Rybrevant.

Pregnancy and fertility – information for women

Tell your doctor or nurse before you are given Rybrevant if you are pregnant, think you might be pregnant or are planning to have a baby.

If you become pregnant while being treated with this medicine, tell your doctor or nurse straight away. You and your doctor will decide if the benefit of having the medicine is greater than the risk to your baby.

Pregnancy and fertility – information for men

If your partner becomes pregnant while you are taking this medicine, tell your doctor straight away.

Men should not donate or store semen during and for 3 months after stopping treatment with Rybrevant.

Breast-feeding

You should not breast-feed while taking this medicine and for 3 months after stopping treatment with Rybrevant.

Driving and using machines

If you feel tired or feel dizzy after taking Rybrevant, do not drive or use machines.

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

Interactions with other drugs, vitamins, minerals, natural supplements or alternative medicines have not been established with Rybrevant.

How you are given Rybrevant:

- Rybrevant will be given to you by a healthcare professional in a healthcare setting.
- A nurse or doctor will give you Rybrevant through a drip into a vein ('intravenous infusion') over several hours.

Usual dose:

Your doctor will determine your dose of Rybrevant. The dose of Rybrevant will depend on your body weight at the start of your therapy. In the first week your doctor will give you the Rybrevant dose split over two days.

The usual dose of Rybrevant when given alone is:

- 1050 mg if you weigh less than 80 kg (175 lbs).
- 1400 mg if you weigh more than or equal to 80 kg (175 lbs).

When given alone, Rybrevant is given as follows:

- once a week for the first 4 weeks
- then once every 2 weeks starting at Week 5 as long as you are getting benefit from the treatment.

The usual dose of Rybrevant when given with chemotherapy, is:

- 1400 mg for the first 4 doses and 1750 mg for subsequent doses if you weigh less than 80 kg (175 lbs).
- 1750 mg for the first 4 doses and 2100 mg for subsequent doses if you weigh more than or equal to 80 kg (175 lbs).

When given with chemotherapy, Rybrevant is given as follows:

- once a week for the first 4 weeks
- then once every 3 weeks starting at Week 7 as long as you are getting benefit from the treatment.

Overdose:

This medicine will be given by your doctor or nurse. In the unlikely event that you are given too much (an overdose) your doctor will check you for side effects.

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

If you miss an appointment to get Rybrevant:

- If you miss an appointment, call your doctor and make another appointment as soon as possible
- It is very important to go to all of your appointments

What are possible side effects from using Rybrevant?

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

Very common side effects (may affect more than 1 in 10 people (>10%))

- Rash
- Infected skin around the nail
- Dry skin
- Itching
- Constipation or diarrhoea
- Sores in mouth
- Nausea or vomiting
- Feeling very tired
- Swollen hands, face, ankles or feet
- Decreased appetite
- Dizziness
- Fever
- Changes in eyesight
- Muscle pain
- Cough
- Shortness of breath

Common side effects (may affect between 1 and 10 people out of every 100)

- Hemorrhoids
- Stomach pain
- Muscle aches and joint pain

Rybrevant can cause abnormal blood tests. Your doctor will decide when to perform blood tests and will interpret the results. Rybrevant may cause:

- low level of 'albumin' in the blood
- increased level of liver enzymes 'alanine aminotransferase', 'aspartate aminotransferase', and 'gamma-glutamyltransferase' in the blood
- low level of sodium in the blood
- low number of white blood cells
- low number of red blood cells
- low number of platelets, cells that help blood to clot

- high level of 'bilirubin' in the blood
- low level of phosphate in the blood
- low level of protein in the blood
- high level of sugar in the blood
- increased level of blood lactate dehydrogenase
- increased level of 'creatinine' in the blood

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
VERY COMMON (affecting more than 1 in 10 people)		
Infusion reactions: chills, nausea, feeling short of breath, flushing, chest discomfort, vomiting, or any side effect during an infusion. This can happen especially with the first dose.		v
Skin and Nail Problems: rash (including acne), infected skin around the nails, dry skin, itching, pain, blistering, and redness. Tell your doctor if your skin or nail problems get worse.		v
Eye Problems: dry eye, eye redness, itchy eyes, problems/changes with vision, growth of eyelashes, inflamed cornea (front part of the eye), excessive tearing		v
COMMON (affecting between 1 to 10 people out of every 100)		
Inflammation of the lungs: sudden difficulty in breathing, cough, or fever. This could lead to permanent damage ('interstitial lung disease')		v

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

Storage:

Rybrevant will be stored at a hospital or clinic.

Store in a refrigerator at 2°C to 8°C. Do not freeze. Protect from light.

If you want more information about Rybrevant:

- Talk to your healthcare professional
- For questions or concerns, please contact the manufacturer, Janssen Inc., at www.janssen.com/canada
- 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 (<https://www.janssen.com/canada>), or by calling 1-800-567-3331.

This leaflet was prepared by Janssen Inc.
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