

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr RYBREVANT® SC

amivantamab injection

This Patient Medication Information is written for the person who will be taking **RYBREVANT SC**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **RYBREVANT SC**, talk to a healthcare professional.

If your cancer is treated with **RYBREVANT SC** in combination with another medication called lazertinib, read the Patient Medication Information for lazertinib as well as this one.

What RYBREVANT SC is used for:

RYBREVANT SC 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 SC 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 SC can be prescribed for you:

- after chemotherapy stops working against your cancer.

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

RYBREVANT SC can be prescribed for you:

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

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.

How RYBREVANT SC works:

Amivantamab is an antibody, that is a type of protein, that has been designed to recognize 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 SC 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 SC may be given in combination with other anti-cancer medicines, such as chemotherapy (carboplatin and pemetrexed) or lazertinib. It is important that you also read the package inserts for these other medicines. If you have any questions about these medicines, ask your healthcare professional.

The ingredients in RYBREVANT SC are:

Medicinal ingredient: Amivantamab

Non-medicinal ingredients: Recombinant human hyaluronidase (rHuPH20), EDTA disodium salt dihydrate, glacial acetic acid, L-methionine, polysorbate 80, sodium acetate trihydrate, sucrose, and water for injections.

RYBREVANT SC comes in the following dosage form(s):

RYBREVANT SC is provided as a solution that is administered by subcutaneous (under the skin) injection. It comes in 160 mg / mL in the following dosage forms:

- 1600 mg / 10 mL
- 2240 mg / 14 mL
- 2400 mg / 15 mL
- 3520 mg / 22 mL

Do not use RYBREVANT SC if:

- you are allergic to amivantamab or any other ingredients of RYBREVANT SC (see **"The ingredients in RYBREVANT SC are:"**)

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

- have a history of lung or breathing problems
- you have suffered from inflammation of your lungs (a condition called 'interstitial lung disease' or 'pneumonitis')
- have or have ever had heart problems
- are over the age of 65

Other warnings you should know about:

Administration-related reactions: Before each injection of RYBREVANT SC, you will be given medicines which help to lower the chance of administration-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 SC if you get any of the following side effects:

- Any side effects during RYBREVANT SC administration.
- Sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs.
- Sharp chest pain, shortness of breath, rapid breathing, leg pain, or swelling of your arms or legs when RYBREVANT SC is given in combination with lazertinib, that may suggest a blood clot in the veins and may lead to death. Your doctor may give you additional medication to help prevent blood clots during your treatment.
- Skin and nail problems. To reduce the risk and severity of skin and nail problems, wear protective clothing, apply broad-spectrum UVA/UVB sunscreen, and use moisturisers (ceramide-based or other formulations that provide long-lasting skin hydration and without drying components are preferred) regularly on your face and whole body (except scalp) while taking RYBREVANT SC. You will need to keep out of the sun and continue doing this for 2 months after you stop treatment. Your healthcare professional may recommend that you start an antibiotic(s) (topical and/or oral) and an antiseptic to wash your hands and feet to reduce the risk and severity of skin and nail problems. If you experience skin and/or nail reactions during treatment, your healthcare professional may treat you with a medicine(s) or send you to see a skin specialist (dermatologist).
- 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.

Other warnings you should know about:**Children and adolescents**

- Do not give RYBREVANT SC to children or young people below 18 years of age. This is because it is not known whether 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 SC.

Pregnancy and fertility - information for women

Tell your doctor or nurse before you are given RYBREVANT SC 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 healthcare professional straight away.

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

Breastfeeding

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

Driving and using machines

- If you feel tired, feel dizzy, or if your eyes are irritated or vision is affected after taking RYBREVANT SC, 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 SC.

How to take RYBREVANT SC:

- RYBREVANT SC will be given to you by a healthcare professional as an injection under your skin (subcutaneous injection) over approximately 5 minutes per injection.
- It is given in the stomach area (abdomen), not in other sites of the body, and not into areas of the abdomen where the skin is red, bruised, tender, hard or where there are tattoos or scars. If you experience pain during the injection, the doctor or nurse may interrupt the injection and give you the remaining injection in another area of your abdomen.

Usual dose:

Your doctor will work out your dose of RYBREVANT SC. The dose of RYBREVANT SC will depend on your body weight at the start of your therapy. You will be treated with RYBREVANT SC once every 2, or 3, or 4 weeks according to the treatment your doctor decides for you.

The recommended dose of RYBREVANT SC when given alone or in combination with lazertinib every 4 weeks is:

- 1600 mg for the first 4 doses and 3520 mg for subsequent doses if you weigh less than 80 kg.
- 2240 mg for the first 4 doses and 4640 mg for subsequent doses if you weigh more than or equal to 80 kg.

RYBREVANT SC is given every 4 weeks as follows:

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

The recommended dose of RYBREVANT SC when given alone or in combination with lazertinib every 2 weeks is:

- 1600 mg if you weigh less than 80 kg.
- 2240 mg if you weigh more than or equal to 80 kg.

RYBREVANT SC is given every 2 weeks 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 recommended dose of RYBREVANT SC when given with chemotherapy every 3 weeks is:

- 1600 mg for the first dose and 2400 mg for subsequent doses if you weigh less than 80 kg.
- 2240 mg for the first dose and 3360 mg for subsequent doses if you weigh more than or equal to 80 kg.

RYBREVANT SC is given every 3 weeks 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.

Medicines given during treatment with RYBREVANT SC

Before each injection of RYBREVANT SC, you will be given medicines which help to lower the chance of administration-related reactions and infusion-related reactions. These may include:

- medicines for an allergic reaction (antihistamines)
- medicines for inflammation (corticosteroids)
- medicines for fever (such as paracetamol)

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

Overdose:

This medicine will be given by your healthcare professional. 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 SC, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

It is very important to go to all your appointments. If you miss an appointment, make another appointment as soon as possible.

If you have any further questions on the use of this medicine, ask your healthcare professional.

Possible side effects from using RYBREVANT SC:

These are not all the possible side effects you may have when taking RYBREVANT SC. 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)

- Rash
- Infected skin around the nail
- Dry skin
- Itching
- Constipation or diarrhoea
- Sores in the 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
- Veins blocked by a blood clot when RYBREVANT SC is used with lazertinib
- Tingling, numbness, pain or loss of pain sensation when RYBREVANT SC is used with lazertinib

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

- Hemorrhoids
- Stomach pain
- Muscle aches and joint pain
- irritation or pain where the injection is given
- Bleeding (nosebleed, bleeding gums, blood in urine) when RYBREVANT SC is used with lazertinib

RYBREVANT SC can cause abnormal blood test. Your healthcare professional will decide when to perform blood tests and will interpret the results. RYBREVANT SC 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

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common (affecting more than 1 in 10 people)			
Administration Reactions: chills, feeling short of breath, feeling sick (nausea), flushing, chest discomfort, and fever. This can happen especially with the first dose. Your doctor may give you other medicines, or the injection may need to be stopped.		√	
Skin and Nail Problems: rash (including acne), infected skin around the nails, dry skin, itching, pain, blistering, and redness. Tell your healthcare professional if your skin or nail problems get worse.		√	
Venous Thromboembolism (a blood clot in the veins, especially in the lungs or legs when used in combination with lazertinib): sharp chest pain, shortness of breath, rapid breathing, leg pain and swelling of your arms or legs. Can be fatal.		√	
Eye Problems: dry eye, eye redness, itchy eyes, problems/changes with vision, growth of eyelashes, inflamed cornea (front part of the eye), excessive tearing, and swollen eyelid		√	
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').		√	

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 (canada.ca/drug-device-reporting) 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 SC will be stored at a hospital or clinic.

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

Keep out of reach and sight of children.

If you want more information about RYBREVANT SC:

- Talk to your healthcare professional
- For questions or concerns, please contact the manufacturer, Janssen Inc., at innovativemedicine.jnj.com/canada
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website (innovativemedicine.jnj.com/canada); or by calling 1-800-567-3331.

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