# RYBREVANT® SC

## Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the full CMI for further details.

## 1. Why am I receiving RYBREVANT SC?

RYBREVANT SC contains the active ingredient amivantamab.

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 cancer changes in a gene called epidermal growth factor receptor (EGFR).

For more information, see Section 1. Why am I receiving RYBREVANT SC? in the full CMI.

## 2. What should I know before I receive RYBREVANT SC?

Do not receive if you have ever had an allergic reaction to any of the ingredients listed at the end of the full CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant, plan to become pregnant, are trying to make your partner pregnant or are breastfeeding.**

For more information, see Section 2. What should I know before I receive RYBREVANT SC? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with RYBREVANT SC and affect how it works.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

## 4. How do I receive RYBREVANT SC?

RYBREVANT SC will be given to you by a doctor or nurse. It is given as an injection under your skin ("subcutaneous injection") over approximately 5 minutes. Multiple injections may be given for higher doses 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.

More information can be found in Section 4. How do I receive RYBREVANT SC? in the full CMI.

## 5. What should I know while receiving RYBREVANT SC?

| | |
|---|---|
| **Things you should do** | • **Call your doctor or nurse straight away if you experience any of the following:** any side effect during the injection of RYBREVANT SC; sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs; blood clots; skin or nail problems; eye problems.<br>• Both men and women receiving RYBREVANT SC and their partners must use a reliable method of contraception (such as condoms) during and for 3 months after ceasing treatment with RYBREVANT SC.<br>• If you become pregnant or your partner becomes pregnant while receiving RYBREVANT SC, tell your doctor immediately. |
| **Driving or using machines** | • Be careful before you drive or use any machines or tools until you know how RYBREVANT SC affects you. Some of the side effects of RYBREVANT SC listed in section 6 may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines. |

For more information, see Section 5. What should I know after receiving RYBREVANT SC? in the full CMI.

## 6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are: signs of a reaction to the injection such as chills, feeling short of breath, nausea, flushing, chest discomfort, and fever. Skin problems such as rash (including acne), infected skin around the nails, dry skin, itching, pain, redness and life-threatening rash with blisters and peeling skin over much of the body. Signs of blood clots such as sharp chest pain, shortness of breath, rapid breathing, leg pain, and swelling of your arms or legs. Eye problems such as dry eye, eye redness, itchy eyes, problems with vision, growth of eyelashes, inflamed cornea (front part of the eye) or inflammation inside the eye that may affect vision. Signs of any lung problems, such as sudden difficulty in breathing, cough, or fever. For more information, including serious side effects and what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

# RYBREVANT® SC

**Active ingredient(s):** *amivantamab*

## Consumer Medicine Information (CMI)

This CMI provides important information about using RYBREVANT SC. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RYBREVANT SC.**

**Where to find information in this CMI:**


1. Why am I receiving RYBREVANT SC?
2. What should I know before I receive RYBREVANT SC?
3. What if I am taking other medicines?
4. How do I receive RYBREVANT SC?
5. What should I know while receiving RYBREVANT SC?
6. Are there any side effects?
7. Product details


## 1. Why am I receiving RYBREVANT SC?

**RYBREVANT SC contains the active ingredient amivantamab.**

**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 cancer changes in a gene called 'EGFR'.**

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 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.

## 2. What should I know before I receive RYBREVANT SC?

### Warnings

### Do not receive RYBREVANT SC if:

- you are allergic to amivantamab, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

### Check with your doctor, pharmacist or nurse if you:

- have suffered from inflammation of your lungs (a condition called 'interstitial lung disease' or 'pneumonitis')
- have any other medical conditions
- take any medicines for any other condition

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given RYBREVANT SC.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

### Pregnancy and breastfeeding

Like most medicines used to treat cancer, RYBREVANT SC is not recommended for use during pregnancy. If a pregnant person takes RYBREVANT SC, it could harm the unborn baby.

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are trying to make your partner pregnant.

Both men and women receiving RYBREVANT SC and their partners must use a reliable method of contraception (such as condoms) during and for 3 months after ceasing treatment with RYBREVANT SC.

Male patients must not donate sperm during treatment with RYBREVANT SC and for 3 months after completing treatment.

If you or your partner becomes pregnant while you are being treated with this medicine, tell your doctor or nurse straight away.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if RYBREVANT SC passes into breast milk. You and your doctor will decide if the benefit of breast-feeding is greater than the risk to your baby.

You should not breastfeed while being treated with this medicine and for 3 months after ceasing treatment with RYBREVANT SC.

### Children and adolescents below 18 years of age

Do not give RYBREVANT SC to children or young people below 18 years of age. This is because it is not known how the medicine will affect them.

## 3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RYBREVANT SC.**

## 4. How do I receive RYBREVANT SC?

RYBREVANT SC can be given to you:

- as the first medicine you receive for your cancer in combination with another medicine called 'lazertinib'
- as the first medicine you receive for your cancer in combination with chemotherapy
- in combination with chemotherapy after failure of prior therapy with EGFR tyrosine kinase inhibitor (TKI), or
- after chemotherapy stops working against your cancer

### How much you will be given

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, 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 2 weeks is:
  - 1600 mg if you weigh less than 80 kg.
  - 2240 mg if you weigh more than or equal to 80 kg.
- 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 subsequence doses if you weigh less than 80 kg.
  - 2240 mg for the first 4 doses and 4640 mg for subsequence doses if you weigh more than or equal to 80 kg.
- 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.

If your weight changes, it does not mean that the dose has to be changed.

### How it is given

RYBREVANT SC will be given to you by a doctor or nurse as an injection under your skin (subcutaneous injection) over approximately 5 minutes. Multiple injections may be given for higher doses. 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.

#### When it is given

RYBREVANT SC is given every 2 weeks when given alone or in combination with lazertinib 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.

RYBREVANT SC is given every 4 weeks when given alone or in combination with lazertinib 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.

RYBREVANT SC is given every 3 weeks when given with chemotherapy 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. 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.

### If you miss an appointment to receive RYBREVANT SC

- It is very important to go to all your appointments to make sure your treatment is working.
- If you miss an appointment, tell your doctor and arrange another visit as soon as possible.

### If you are given too much RYBREVANT SC

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

## 5. What should I know while receiving RYBREVANT SC?

### Things you should do

### Call your doctor or nurse straight away while receiving RYBREVANT SC if you get any of the following side effects:

- Any side effect during the injection of RYBREVANT SC (see Section 6. Are there any side effects?).
- 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 can be life threatening. Your doctor may give you additional

medication to help prevent blood clots during your treatment.

- Skin or nail problems. To reduce the risk of and severity skin or nail problems, wear protective clothing, apply broad-spectrum UVA/UVB sunscreen, and use alcohol-free moisturisers (ceramide-based or other formulations that provide long-lasting skin hydration and without drying components are preferred) daily 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 doctor may recommend that you start an antibiotic(s) and an antiseptic to wash your hands and feet to reduce the risk and severity of skin and nail problems, may treat you with a medicine(s), or send you to see a skin specialist (dermatologist) if you get skin and nail reactions during 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.

**Remind any doctor, dentist or pharmacist you visit that you are using RYBREVANT SC.**

**Both men and women receiving RYBREVANT SC and their partners must use a reliable method of contraception (such as condoms) during and for 3 months after ceasing treatment with RYBREVANT SC.**

**If you become pregnant or your partner becomes pregnant while receiving RYBREVANT SC, tell your doctor immediately.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how RYBREVANT SC affects you.**

Some of the side effects of RYBREVANT SC listed in section 6 may temporarily affect your ability to drive or use machines.

Wait until these effects have worn off before you drive or use 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.

### Looking after your medicine

RYBREVANT SC is usually stored in the hospital, clinic or at the pharmacy.

Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

| Less serious side effects | What to do |
|---|---|
| • irritation or pain where the injection is given<br>• constipation<br>• diarrhoea<br>• sores in the mouth<br>• swelling caused by fluid build up in the body<br>• nausea<br>• vomiting<br>• decreased appetite<br>• abdomen or stomach pain<br>• haemorroids<br>• feeling very tired or weak<br>• feeling dizzy<br>• headache<br>• fever<br>• muscle or joint pain<br>• numbness or weakness of the arms and legs<br>• bleeding<br>• nail problems<br>• ulcer (sore) on the skin<br>• changes in certain blood tests<br>  ○ low level of the protein 'albumin' in the blood<br>  ○ increased level of the liver enzyme 'alanine aminotransferase' in the blood<br>  ○ increased level of the liver enzyme 'aspartate aminotransferase' in the blood<br>  ○ increased level of the enzyme 'alkaline phosphatase' in the blood<br>  ○ low level of calcium in the blood<br>  ○ low level of magnesium in the blood<br>  ○ low level of potassium in the blood<br>  ○ decreased level of sodium in the blood<br>  ○ low number of a type of white blood cell (neutrophils)<br>  ○ low number of 'platelets' (cells that help blood to clot)<br>  ○ decreased level of haemoglobin in the blood<br>  ○ decreased number of a type of white blood cell (lymphocytes) | **Speak to your doctor if you have any of these less serious side effects and they worry you.** |

| Less serious side effects | What to do |
|---|---|
| ○ decreased level of white blood cells in the blood<br>○ increased level of 'creatinine' in the blood<br>○ increased level of 'gamma glutamyl transferase' in the blood | |

### Serious side effects

| Serious side effects | What to do |
|---|---|
| **Signs of a reaction to the injection, such as:**<br>• chills<br>• fever<br>• nausea<br>• feeling short of breath<br>• flushing<br>• chest discomfort<br>This can happen especially with the first dose. Your doctor may give you other medicines, or the injection may need to be slowed down or stopped. | **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** |
| **Signs of any lung problems, such as:**<br>• sudden difficulty in breathing or shortness of breath<br>• cough<br>• fever<br>This could lead to permanent damage ('interstitial lung disease').<br>Symptoms may be similar to symptoms from lung cancer. Tell your doctor right away if you get any new or worsening lung symptoms.<br>Your doctor may wish to stop RYBREVANT SC if you get this side effect. | |
| **Signs of blood clots, such as:**<br>• sharp chest pain<br>• shortness of breath<br>• rapid breathing<br>• leg pain<br>• swelling of arms or legs.<br>RYBREVANT SC, when given in combination with lazertinib, may cause blood clots in the veins, especially in the lungs or legs. | |
| **Skin problems, such as:**<br>• rash (including acne)<br>• infected skin around the nails<br>• dry skin<br>• itching<br>• pain<br>• redness<br>• life threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis).<br>Tell your doctor if your skin or nail problems get worse, or if it is accompanied by fever, chills, aching muscles and generally feeling unwell. | |
| **Eye problems, such as:**<br>• dry eye<br>• eye redness<br>• itchy eyes<br>• problems with vision<br>• growth of eyelashes<br>• inflamed cornea (front part of the eye)<br>• inflammation inside the eye that may affect vision | |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

### What RYBREVANT SC contains

| | |
|---|---|
| **Active ingredient (main ingredient)** | Amivantamab<br>1600 mg in each 10 mL vial<br>2240 mg in each 14 mL vial<br>2400 mg in each 15 mL vial<br>3520 mg in each 22 mL vial |
| **Other ingredients (inactive ingredients)** | • Disodium edetate<br>• Glacial acetic acid<br>• Methionine<br>• Polysorbate 80<br>• Sodium acetate trihydrate<br>• Sucrose<br>• Vorhyaluronidase alfa (recombinant human hyaluronidase; rHuPH20)<br>• Water for injections |

**Do not receive this medicine if you are allergic to any of these ingredients.**

## What RYBREVANT SC looks like

RYBREVANT SC is a colourless to pale yellow liquid.

RYBREVANT SC is available in cartons containing 1 glass vial with a rubber stopper and aluminium seal with a flip off cap.

1600 mg / 10 mL AUST R 460585

2240 mg / 14 mL AUST R 460625

2400 mg / 15 mL AUST R 513053

3520 mg / 22 mL AUST R 513068

## Who distributes RYBREVANT SC

JANSSEN-CILAG Pty Ltd

17 Khartoum Rd

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

This CMI was prepared on 25 August 2026.