

Package leaflet: Information for the patient

RYBREVANT 50 mg/mL concentrate for solution for infusion amivantamab

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What RYBREVANT is and what it is used for
2. What you need to know before you are given RYBREVANT
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1. What RYBREVANT is and what it is used for

What RYBREVANT is

RYBREVANT is a cancer medicine that contains the active substance ‘amivantamab’.

What RYBREVANT is used for

RYBREVANT is used in adults with a type of cancer called ‘non-small cell lung cancer’ that has spread in your body and has certain cancer changes (Exon 20 insertion mutations) in a gene called ‘EGFR’. It is used if you have already received treatment for your lung cancer with platinum chemotherapy.

How RYBREVANT works

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.

2. What you need to know before you are given RYBREVANT

Do not use RYBREVANT if

- you are allergic to amivantamab or any of the other ingredients of this medicine (listed in section 6).

Do not use RYBREVANT if the above applies to you. If you are not sure, talk to your doctor or nurse before you are given RYBREVANT.

Warnings and precautions

Tell your doctor or nurse before you are given RYBREVANT if:

- you have suffered from inflammation of your lungs (a condition called ‘interstitial lung

disease' or 'pneumonitis')

Tell your doctor or nurse straight away while taking RYBREVANT if you get any of the following side effects (see Section 4 for more information):

- Any side effect during the intravenous infusion (drip into a vein) of RYBREVANT.
- Sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs.
- Skin 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

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

Other medicines and RYBREVANT

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines you can get without a prescription and herbal medicines.

Contraception

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

Pregnancy

- 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.

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.

3. How RYBREVANT is given

How much is given

Your doctor will work out your dose of RYBREVANT. The dose of RYBREVANT will depend on your body weight at the start of your therapy.

The recommended dose of RYBREVANT is:

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

RYBREVANT is given as follows:

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

In the first week your doctor will give you the RYBREVANT dose split over two days.

How the medicine is given

RYBREVANT will be given to you by a doctor or nurse. It is given as a drip into a vein ('intravenous infusion') over several hours.

Medicines given during treatment with RYBREVANT

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 paracetamol)

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

If you are given more RYBREVANT than you should

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 forget your appointment to have RYBREVANT

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor or nurse straight away if you notice the following serious side effects:

Very Common (may affect more than 1 in 10 people):

- **Signs of a reaction to the infusion of RYBREVANT** – such as, chills, nausea, feeling short of breath, flushing, chest discomfort, and vomiting during an infusion. This can happen especially with the first dose. Your doctor may give you other medicines, or the infusion may need to be slowed down or stopped.
- **Skin and nail problems** - such as rash (including acne), infected skin around the nails, dry skin, itching, pain, and redness. Tell your doctor if your skin or nail problems get worse. Your doctor may give you extra treatment for your skin or may wish to adjust the dose or stop RYBREVANT.

Common (may affect up to 1 in 10 people):

- **Eye problems** - such as dry eye, eye redness, itchy eyes, problems with vision, growth of eyelashes, inflamed cornea (front part of the eye), and inflammation inside the eye that may affect vision
- **Signs of an inflammation in the lungs** – such as sudden difficulty in breathing, cough, or fever. This could lead to permanent damage ('interstitial lung disease'). Your doctor may wish to stop RYBREVANT if you get this side effect.

Tell your doctor straight away if you notice any of the above serious side effects.

Other side effects

Very common (may affect more than 1 in 10 people):

- feeling very tired
- swelling caused by fluid build up in the body
- sores in the mouth
- nausea
- constipation or diarrhoea

- vomiting
- decreased appetite
- feeling dizzy
- muscle aches
- low level of the protein 'albumin' in the blood
- increased level of the liver enzyme 'alanine aminotransferase' in the blood
- increased level of the enzyme 'aspartate aminotransferase' in the blood
- low level of potassium in the blood
- low level of magnesium in the blood
- increased level of the enzyme 'alkaline phosphatase' in the blood
- low level of calcium in the blood

Common (may affect up to 1 in 10 people)

- Stomach pain

Uncommon (may affect up to 1 in 100 people)

- life-threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store RYBREVANT

RYBREVANT will be stored at the hospital or clinic. Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What RYBREVANT contains

- The active substance is amivantamab. One mL of concentrate contains 50 mg of amivantamab. Each vial of 7 mL concentrate contains 350 mg of amivantamab.
- The other ingredients are ethylenediaminetetraacetic acid (EDTA), histidine, methionine, polysorbate 80, sucrose, and water for injections.

What RYBREVANT looks like and contents of the pack

RYBREVANT is a concentrate for solution for infusion and is a colourless to pale yellow liquid. RYBREVANT is supplied as a carton pack containing 1 glass vial.

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