

Package leaflet: Information for the patient

Rybrevent 350 mg 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 Rybrevent is and what it is used for
2. What you need to know before you are given Rybrevent
3. How Rybrevent is given
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1. What Rybrevent is and what it is used for

What Rybrevent is

Rybrevent is a cancer medicine. It contains the active substance ‘amivantamab’, which is an antibody (type of protein) designed to recognise and attach to specific targets in the body.

What Rybrevent is used for

Rybrevent is used in adults with a type of lung cancer called ‘non-small cell lung cancer’. It is used when the cancer has spread to other parts of your body and has gone through certain changes in a gene called ‘EGFR’.

Rybrevent can be prescribed for you:

- as the first medicine you receive for your cancer in combination with lazertinib.
- in combination with chemotherapy after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI).
- as the first medicine you receive for your cancer in combination with chemotherapy, or
- when chemotherapy is no longer working against your cancer.

How Rybrevent works

The active substance in Rybrevent, amivantamab, targets two proteins found on cancer cells:

- epidermal growth factor receptor (EGFR), and
- mesenchymal-epithelial transition factor (MET).

This medicine 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.

Rybrevent 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.

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

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 this medicine if the above applies to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

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’).
- you have previous history of blood clots in the veins.

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

- Any side effect while the medicine is being given into your vein.
- Sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs.
- When used with another drug called lazertinib; sharp chest pain, shortness of breath, rapid breathing, leg pain, or swelling of your arms or legs - 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 the course of your treatment and will monitor you for potential symptoms.
- 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 this medicine. You will need to continue doing 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 this medicine to children or young people below 18 years of age. This is because it is not known whether the medicine is safe and effective in this age group.

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 Rybrevant treatment and for 3 months after stopping treatment.

Pregnancy

- Tell your doctor or nurse before you are given this medicine if you are pregnant, think you might be pregnant, or are planning to have a baby.
- It is possible that this medicine may harm an unborn 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 unborn baby.

Breast-feeding

It is not known if Rybrevant passes into breast milk. Ask your doctor for advice before being given this medicine. You and your doctor will decide if the benefit of breast-feeding is greater than the risk to your baby.

Driving and using machines

If you feel tired, feel dizzy, or if your eyes are irritated or vision is affected after taking Rybrevant, do not drive or use machinery.

Rybrevant contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially

'sodium-free'. However, before Rybrevant is given to you, it may be mixed with a solution that contains sodium. Talk to your doctor if you are on a low salt diet.

Rybrevant contains polysorbate

This medicine contains 0.6 mg of polysorbate 80 in each mL, which is equivalent to 4.2 mg per 7 mL vial. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How Rybrevant is given

How much is given

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

The recommended dose of Rybrevant every 2 weeks is:

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

The recommended dose of Rybrevant every 3 weeks is:

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

How the medicine is given

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

Rybrevant is given as follows:

- once a week for the first 4 weeks
- then once every 2 weeks starting at week 5 or once every 3 weeks starting at week 7, for as long as you keep getting benefit from the treatment.

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

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 – such as chills, feeling short of breath, feeling sick (nausea), flushing, chest discomfort, and vomiting while the medicine is being given. 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.
- When given together with another medicine called ‘lazertinib’, a blood clot in the veins, especially in the lungs or legs can occur. Signs may include sharp chest pain, shortness of breath, rapid breathing, leg pain, and swelling of your arms or legs.
- 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 and/or nails 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, swollen eyelid, itchy eyes, problems with vision, growth of eyelashes.
- 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.

Uncommon (may affect up to 1 in 100 people):

- inflamed cornea (front part of the eye)
- inflammation inside the eye that may affect vision
- life-threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis).

The following side effects have been reported in clinical studies with Rybrevant in combination with lazertinib:

Other side effects

Talk to your doctor if you get any other side effects. These can include:

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

- low level of the protein ‘albumin’ in the blood
- swelling caused by fluid build up in the body
- sores in the mouth
- increased level of the enzyme ‘alanine aminotransferase’ in the blood
- feeling very tired
- constipation
- diarrhoea
- increased level of the enzyme ‘aspartate aminotransferase’ in the blood
- decreased appetite
- low level of calcium in the blood
- nausea
- low level of potassium in the blood
- feeling dizzy
- muscle aches
- increased level of the enzyme ‘alkaline phosphatase’ in the blood
- fever
- vomiting
- stomach pain.

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

- haemorrhoids
- low level of magnesium in the blood

The following side effects have been reported in clinical studies with Rybrevant when given alone:

Other side effects

Tell your doctor if you notice any of the following side effects.

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

- low level of the protein ‘albumin’ in the blood
- swelling caused by fluid build up in the body
- feeling very tired
- sores in the mouth
- constipation or diarrhoea
- decreased appetite
- increased level of the liver enzyme ‘alanine aminotransferase’ in the blood, a possible sign of liver problems
- increased level of the enzyme ‘aspartate aminotransferase’ in the blood, a possible sign of liver problems
- feeling dizzy
- increased level of the enzyme ‘alkaline phosphatase’ in the blood
- muscle aches
- fever
- low level of calcium in the blood

Common (may affect up to 1 in 10 people)

- stomach pain
- low level of potassium in the blood
- low level of magnesium in the blood
- haemorrhoids

The following side effects have been reported in clinical studies with Rybrevant in combination with chemotherapy:

Other side effects

Tell your doctor if you notice any of the following side effects:

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

- low number of a type of white blood cell (neutropenia)
- low number of ‘platelets’(cells that help blood to clot)
- blood clot in the veins
- feeling very tired
- nausea
- sores in the mouth
- constipation
- swelling caused by fluid build up in the body
- decreased appetite
- low level of the protein ‘albumin’ in the blood
- increased level of the liver enzyme ‘alanine aminotransferase’ in the blood, a possible sign of liver problems
- increased level of the enzyme ‘aspartate aminotransferase’ in the blood, a possible sign of liver problems
- vomiting
- low level of potassium in the blood

- diarrhoea
- fever
- low level of magnesium in the blood
- low level of calcium in the blood

Common (may affect up to 1 in 10 people)

- increased level of the enzyme ‘alkaline phosphatase’ in the blood
- stomach pain
- feeling dizzy
- haemorrhoids
- muscle aches

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: <https://yellowcard.mhra.gov.uk/> 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 and the vial label after “EXP”. The expiry date refers to the last day of that month.

Chemical and physical in-use stability has been demonstrated for 10 hours at 15°C to 25°C in room light. From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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 for solution for infusion contains 50 mg of amivantamab. One vial of 7 mL concentrate contains 350 mg of amivantamab.
- The other ingredients are ethylenediaminetetraacetic acid (EDTA), L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose, and water for injections (see section 2).

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. This medicine is available in a carton pack containing 1 glass vial of 7 mL of concentrate.

Marketing Authorisation Holder

Janssen-Cilag Ltd

50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

Manufacturer

Janssen Biologics B.V.
Einsteinweg 101
2333 CB Leiden
The Netherlands

For information in large print, tape, CD or Braille, telephone 0800 7318450.

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