Package leaflet: Information for the patient

Rybrevant 1600 mg solution for injection
Rybrevant 2240 mg solution for injection
Rybrevant 2400 mg solution for injection
Rybrevant 3520 mg solution for injection
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. 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 Rybrevant is used for
Rybrevant 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’.

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

How Rybrevant works
The active substance in Rybrevant, 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.

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.

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 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 injected.
- Sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs. The condition may be life threatening, therefore healthcare professionals will monitor you for potential symptoms.
- When used with another drug called lazertinib; life-threatening side effects (due to blood clots in the veins) may occur. Your doctor will 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 and severity of skin 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 this medicine. 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 problems, and may treat you with a medicine(s), or send you to see a skin specialist (dermatologist) if you get skin 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.

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'.

Rybrevant contains polysorbate
This medicine contains 0.6 mg of polysorbate 80 in each mL, which is equivalent to 6 mg per 10 mL vial, 8.4 mg per 14 mL vial, 9 mg per 15 mL vial, or 13.2 mg per 22 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 solution for subcutaneous injection 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 week for the first 4 weeks, then once every 2, 3 or 4 weeks according to the treatment your doctor decides for you.

<u>Recommended dose of Rybrevant solution for subcutaneous injection when given alone or in combination with lazertinib</u>

Every 4 weeks:
- 1600 mg weekly for the first 4 doses, and then 3520 mg every 4 weeks if you weigh less than 80 kg.
- 2240 mg weekly for the first 4 doses, and then 4640 mg every 4 weeks if you weigh more than or equal to 80 kg.

Every 2 weeks:
- 1600 mg weekly for the first 4 doses, and then every 2 weeks if you weigh less than 80 kg.
- 2240 mg weekly for the first 4 doses, and then every 2 weeks if you weigh more than or equal to 80 kg.

<u>Recommended dose of Rybrevant solution for subcutaneous injection when given in combination with chemotherapy (carboplatin and pemetrexed)</u>

Every 3 weeks:

- 1600 mg for the first dose, then 2400 mg weekly for the next 3 doses, and then every 3 weeks if you weigh less than 80 kg.
- 2240 mg for the first dose, then 3360 mg weekly for the next 3 doses, and then every 3 weeks if you weigh more than or equal to 80 kg.

How the medicine is given
Rybrevant solution for subcutaneous injection will be given to you by a doctor or nurse 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.

Medicines given during treatment with Rybrevant
Before each injection of Rybrevant, you will be given medicines which help 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 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.

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):
- When given together with lazertinib or chemotherapy (carboplatin and pemetrexed), 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.
- Signs of a reaction to the injection - such as 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.

Common (may affect up to 1 in 10 people):
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.
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- Signs of an inflamed cornea, which is the front part of the eye (keratitis) – such as eye pain, sensitivity to light, redness, changes in vision or eye discharge. If you experience these symptoms, you should discontinue use of contact lenses until you have spoken to your doctor.

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).
- Inflammation inside the eye that may affect vision (uveitis).

Other side effects

Very common (may affect more than 1 in 10 people):
- skin rash
- nail problems
- low number of a type of white blood cell (neutropenia)[b]
- low level of the protein 'albumin' in the blood
- feeling very tired
- nausea
- sores in the mouth
- liver problems[a]
- swelling caused by fluid build up in the body (oedema)
- low number of 'platelets' (cells that help blood to clot)[b]
- constipation
- diarrhoea
- decreased appetite
- unusual feeling in the skin (such as tingling or a crawling feeling)[a]
- increased level of the liver enzyme 'alanine aminotransferase' in the blood
- increased level of the liver enzyme 'aspartate aminotransferase' in the blood
- dry skin
- itching
- vomiting
- low level of potassium in the blood
- other eye problems
- low level of calcium in the blood
- muscle aches
- feeling dizzy
- muscle spasms[a]
- fever
- stomach pain
- increased level of the liver enzyme 'alkaline phosphatase' in the blood
- low level of magnesium in the blood.

Common (may affect up to 1 in 10 people):
- haemorrhoids
- irritation or pain where the injection is given
- ulcer (sore) on the skin
- problems with vision
- redness, swelling, peeling or tenderness, mainly on the hands or feet (palmar-plantar erythrodysaesthesia syndrome)
- growth of eyelashes
- hives.[a]

[a] Only seen in combination with lazertinib
[b] Only seen in combination with carboplatin and pemetrexed

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist 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, Website: **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 solution for subcutaneous injection 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.

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

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

Chemical and physical in-use stability of the prepared syringe has been demonstrated up to 24 hours at 2°C to 8°C followed by up to 24 hours at 15°C to 30°C. From a microbiological point of view, unless the method of dose preparation 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.

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 solution contains 160 mg of amivantamab. One vial of 10 mL of solution for injection contains 1600 mg of amivantamab. One vial of 14 mL of solution for injection contains 2240 mg of amivantamab. One vial of 15 mL of solution for injection contains 2400 mg of amivantamab. One vial of 22 mL of solution for injection for injection contains 3520 mg of amivantamab.
- The other ingredients are recombinant human hyaluronidase (rHuPH20), EDTA disodium salt dihydrate, glacial acetic acid, L-methionine, polysorbate 80 (E433), sodium acetate trihydrate, sucrose, and water for injections (see "Rybrevant contains sodium" and "Rybrevant contains polysorbate" in section 2).

What Rybrevant looks like and contents of the pack
Rybrevant solution for subcutaneous injection is a colourless to pale yellow liquid. This medicine is available in a carton pack containing 1 glass vial of 10 mL of solution, 1 glass vial of 14 mL of solution, 1 glass vial of 15 mL of solution or 1 glass vial of 22 mL of solution.

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