PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RYBREVANT

350 mg concentrate for solution for infusion

Amivantamab

Contains sugar: Each 7 mL vial of concentrate for solution for infusion contains 595 mg of sucrose.

Read all of this leaflet carefully before you are given RYBREVANT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

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
3. How RYBREVANT is given
4. Possible side effects
5. How to store RYBREVANT
6. Contents of the pack and other information

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 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 (Exon 20 insertion mutations) in a gene called ‘EGFR’.

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

You must not be given RYBREVANT if

you have previously had a severe hypersensitivity (allergic) reaction to amivantamab or any of the other ingredients of RYBREVANT (listed in section 6).

Warnings and precautions

Tell your doctor or healthcare professional before being given RYBREVANT:

Special care should be taken with 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

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think that you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you are given this medicine.

Pregnancy and fertility – information for women

- 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.

Pregnancy and fertility – information for men

- If your partner becomes pregnant while you are taking this medicine, tell your doctor straight away.
- Men should not donate or store semen during and for 3 months after stopping treatment with RYBREVANT.

Contraception

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

Breastfeeding

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.

RYBREVANT contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 7 mL, that is to say essentially 'sodium-free'.

3. How RYBREVANT is given

Do not share medicines prescribed for you with any other person.

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:

- 1 050 mg if you weigh less than 80 kg.
- 1 400 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 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 to make sure your treatment works. 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.

If you stop treatment with RYBREVANT

You should not stop receiving RYBREVANT without discussing with your doctor first.

4. Possible side effects

RYBREVANT can have side effects. Not all side effects reported for RYBREVANT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving RYBREVANT, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, tell your doctor or nurse straight away or go to the casualty department at your nearest hospital:

Infusion-related reactions

Tell your doctor or nurse straight away if you get any of the following symptoms. This can especially happen with the first dose. You may need other medicines, or the infusion may need to be slowed down or stopped.

- Chills
- nausea,
- feeling short of breath,
- flushing,
- chest discomfort, and
- vomiting during an infusion

Allergic reactions

If any of the following happens, tell your doctor or nurse immediately or go to the casualty department at your nearest hospital:

- swollen face, lips, mouth, tongue or throat

- difficulty swallowing or breathing
- an itchy rash (hives)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RYBREVANT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Eye problems - such as dry eye, problems with vision, itchy eyes, growth of eyelashes, and eye redness
- 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.
- Skin 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.
- swelling caused by fluid build up in the body
- feeling very tired
- sores in mouth
- constipation or diarrhoea
- decreased appetite
- feeling dizzy
- muscle aches
- low level of 'albumin' in the blood
- increased level of the liver enzyme 'alanine aminotransferase' in the blood
- increased level of the liver enzyme ‘aspartate aminotransferase’ in the blood
- increased level of the enzyme ‘alkaline phosphatase’

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

Less frequent side effects

- 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/index/8
By reporting side effects, you can help provide more information on the safety of RYBREVANT.

Alternatively, you may report side effects experienced with RYBREVANT directly to Janssen Pharmaceutica (see section Holder of the Certificate of Registration for contact details or visit www.janssen.com).

5 How to store RYBREVANT

- RYBREVANT will be stored at the hospital or clinic.
- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and label, after 'EXP'. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 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 (i.e. drains or sewerage systems (e.g., toilets). 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), L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose, and water for injections.(see RYBREVANT contains sodium in 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.

RYBREVANT is supplied as a carton pack containing one glass vial.

Holder of certificate of registration

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Access to the corresponding Professional Information

is included in the carton, accompanying this patient information leaflet.