PATIENT INFORMATION

RYBREVANT™ (RYE–breh–vant)

(INN: amivantamab 50 mg/mL)

Injection, for intravenous use

What is RYBREVANT?

RYBREVANT is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic) or cannot be removed by surgery, **and**
- has a certain abnormal epidermal growth factor receptor "EGFR" gene(s) **and**
- whose disease has worsened while on or after chemotherapy that contains platinum.

Your healthcare provider will perform a test to make sure that RYBREVANT is right for you.

It is not known if RYBREVANT is safe and effective in children.

Before you receive RYBREVANT, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of lung or breathing problems.
- are pregnant or plan to become pregnant. RYBREVANT can harm your unborn baby.

  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with RYBREVANT.
  - You should use effective birth control (contraception) during treatment and for 3 months after your final dose of RYBREVANT.
  - Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with RYBREVANT.
- are breastfeeding or plan to breastfeed. It is not known if RYBREVANT passes into your breast milk. Do not breastfeed during treatment and for 3 months after your final dose of RYBREVANT.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive RYBREVANT?

- RYBREVANT will be given to you by your healthcare provider by intravenous infusion into your vein.
- Your healthcare provider will decide the time between doses as well as how many treatments you will receive.
- Your healthcare provider will give you medicines before each dose of RYBREVANT to help reduce the risk of infusion-related reactions.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What should I avoid while receiving RYBREVANT?

RYBREVANT can cause skin reactions. You should limit your time in the sun during and for 2 months after your treatment with RYBREVANT. Wear protective clothing and use sunscreen during treatment with RYBREVANT.

What are the possible side effects of RYBREVANT?

RYBREVANT may cause serious side effects, including:

- **infusion-related reactions.** Infusion-related reactions are common with RYBREVANT and can be severe or serious. Tell your healthcare provider right away if you get any of the following symptoms during your infusion of RYBREVANT:
  - shortness of breath
  - fever
  - chills
  - nausea
  - flushing
  - chest discomfort
  - lightheadedness
  - vomiting
- **lung problems.** RYBREVANT may cause lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you get any new or worsening lung symptoms, including shortness of breath, cough, or fever.
- **skin problems.** RYBREVANT may cause rash, itching, and dry skin. You may use alcohol-free moisturizing cream for dry skin. Tell your healthcare provider right away if you get any skin reactions. Your healthcare provider may treat you with a medicine(s) or send you to see a skin specialist (dermatologist) if you get skin reactions during treatment with RYBREVANT. See "What should I avoid while receiving RYBREVANT?"
- **eye problems.** RYBREVANT may cause eye problems. Tell your healthcare provider right away if you get symptoms of eye problems which may include:
  - eye pain
  - dry eyes
  - eye redness
  - blurred vision
  - changes in vision
  - itchy eyes
  - excessive tearing
  - sensitivity to light

  Your healthcare provider may send you to see an eye specialist (ophthalmologist) if you get eye problems during treatment with RYBREVANT. You should not use contact lenses until your eye symptoms are checked by a healthcare provider.

The most common side effects of RYBREVANT include:

- rash
- infusion-related reactions
- infected skin around the nail
- muscle and joint pain
- shortness of breath
- nausea
- feeling very tired
- swelling of hands, ankles, feet, face, or all of your body
- sores in the mouth
- cough
- constipation
- vomiting
- changes in certain blood tests

Your healthcare provider may temporarily stop, decrease your dose or completely stop your treatment with RYBREVANT if you have serious side effects.
These are not all of the possible side effects of RYBREVANT.

Call your doctor for medical advice about side effects. You may report side effects to FDA.

General information about safe and effective use of RYBREVANT

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider or pharmacist for information about RYBREVANT that is written for health professionals.

What are the ingredients of RYBREVANT?

Active ingredient: amivantamab

Inactive ingredients: EDTA disodium salt dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose, and water for injection.

Nature and contents of container

RYBREVANT (amivantamab) injection is supplied as a colorless to pale yellow preservative-free solution for intravenous infusion in a single-use vial individually packed in a carton.

Storage condition

Store in a refrigerator at 2°C to 8°C (36°F to 46°F).

Do not freeze. Protect from light.

Keep out of reach of children.

Product Name	Manufactured by	Market Authorization Number	Date of Authorization
RYBREVANT	Cilag AG Schaffhausen, Switzerland	1C 15287/65 (NBC)	30 November 2022

Date of revision of the text

23-Sep-2023 (USPIL V May-2021)

Imported by

Janssen-Cilag Ltd.

Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at *aepqcjacth@its.jnj.com*

For any product information, please contact us at *medinfosea@its.jnj.com*

Please see full prescribing information at

https://ndi.fda.moph.go.th/

https://www.fda.moph.go.th/sites/oss/Pages/Main.aspx

Warning according to the announcement from Ministry of Public Health

This medicinal product may cause serious harm. It must be used only under physician's supervision.