Rystiggo®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being given Rystiggo®?

Rystiggo® contains the active ingredient rozanolixizumab. Rozanolixizumab is used to treat generalised myasthenia gravis by impairing the body's inflammatory response. The body's inflammatory response can lead to intense muscle weakness, extreme fatigue, difficulty breathing, difficulty with moving and activities of daily living.
For more information, see Section 1. Why am I being given Rystiggo®? in the full CMI.

2. What should I know before I am given Rystiggo®?

Do not get treated with Rystiggo® if you have ever had an allergic reaction or react to rozanolixizumab or any of the ingredients listed at the end of the CMI and before starting treatment inform your doctor if you have any symptoms of infection. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**
For more information, see Section 2. What should I know before I am given Rystiggo®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rystiggo® and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How am I given Rystiggo®?

- Rystiggo® is given in treatment cycles of 1 dose a week for 6 weeks. A doctor or nurse will administer Rystiggo® to you via an infusion under the skin. Your doctor will decide on when to initiate a treatment cycle based on your symptoms.
- The required dose for each treatment will be calculated by your doctor based on your body weight.
- More instructions can be found in Section 4. How am I given Rystiggo®? in the full CMI.

5. What should I know while on Rystiggo®?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Rystiggo®. • Tell your doctor prior to a vaccination about your treatment with Rystiggo®. This medicine may impair the effectiveness of vaccines. • Have Rystiggo® administered to you by a doctor or a nurse. • Notify your doctor if you develop signs of aseptic meningitis (non-bacterial inflammation of the tissue covering the brain and spinal cord) such as headache with nausea, vomiting, stiff neck, fever, and/or sensitivity to light.
Things you should not do	• Do not use this medicine after the expiry date which is stated on the label and carton after EXP.
Looking after your medicine	• Keep this medicine out of the sight and reach of children. • Store in a refrigerator between 2°Cto 8°C. Do not freeze. Keep in the original carton to protect from light. The Rystiggo vial may be stored at room temperature (up to 25°C) for a single period of maximum 20 days with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 20 days or by the expiry date, whichever occurs first.

For more information, see Section 5. What should I know while on Rystiggo®? in the full CMI.

6. Are there any side effects?

Side effects that need serious medical attention include headache with nausea, vomiting, stiff neck, fever, and/or sensitivity to light. **Common side effects** include headache including migraine (without fever and/or neck stiffness), fever, nose and throat infections, cold sores, diarrhoea, skin rash sometimes with red bumps, painful skin rash with blisters in one part of the body, joint pain and injection site reaction (including injection site rash, redness of the skin, inflammation, discomfort and infusion site pain).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Rystiggo®

Active ingredient(s): *rozanolixizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about Rystiggo®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Rystiggo®.**

Where to find information in this leaflet:

1. Why am I being given Rystiggo®?

Rystiggo® contains the active ingredient rozanolixizumab. Rozanolixizumab is a selective immunosuppressant that decreases the amount of a specific protein in the body that causes inflammation, preventing your body's systems from attacking and destroying connections between nerves and muscles.

Rystiggo® is used to treat generalised myasthenia gravis by impairing the body's inflammatory response.

The body's inflammatory response can lead to intense muscle weakness, extreme fatigue, difficulty breathing, difficulty with moving and activities of daily living.

2. What should I know before I am given Rystiggo®?

Warnings

Do not use Rystiggo® if:

- you are allergic to rozanolixizumab or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- if you have an infection or any symptoms of an infection,
- and if you have hyperprolinemia (a rare genetic disorder in which an excess of the amino acid, proline, builds up in the body). If you have hyperprolinemia, tell your doctor and do not use this medicine unless your doctor has recommended it.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The effects of this medicine in pregnancy are not known. You should not use this medicine if you are pregnant or think that you may be pregnant unless your doctor specifically recommends it.

Children and adolescents

Rystiggo® is not recommended for children and young people under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Vaccination

Tell your doctor prior to a vaccination about your treatment with Rystiggo®. This medicine may impair the effect of vaccines. Vaccination with live-attenuated or live vaccines is not recommended during treatment with Rystiggo®.

Other Medicines

Taking Rystiggo® with other medicines may result in the loss of effect of those medications or impair the effect of Rystiggo®. Tell your doctor if you are taking or planning to take other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Rystiggo®.

4. How am I given Rystiggo®?

How much Rystiggo® is given

Treatment should be administered by a doctor or nurse, as instructed by your doctor.

Rystiggo® is given in treatment cycles of one dose a week for 6 weeks. The weekly dose administered is based on body weight.

The following table gives the recommended total weekly dose of Rystiggo®.

Body Weight	Dose (mg)	Dose (mL)	Number of vials
From 35 to below 50 kg	280 mg	2 mL	1
50 kg to below 70 kg	420 mg	3 mL	2
70 kg to below 100 kg	560 mg	4 mL	2
100 kg or more	840 mg	6 mL	3

When is Rystiggo® given

A dose is given once a week, every week for 6 weeks. This is a treatment cycle.

Your doctor will decide on when to start a treatment cycle based on your symptoms.

How is Rystiggo® administered

A doctor or nurse will administer Rystiggo® by an infusion under the skin. It will be injected in the lower right or lower left part of your stomach below the belly button.

Injection should not be given into areas where the skin is tender, bruised, red or hard.

Before Rystiggo® is administered to you, the vials will be removed from the refrigerator for 30 to 120 minutes, to allow the product to reach room temperature.

Each vial of solution for injection must be used only once. Any unused solution should be discarded.

Each injection is done using an infusion pump set at a flow rate up to 20 ml/hr.

An Instruction for Use for Healthcare Professionals Handling Rystiggo® is enclosed in the pack.

If you miss a dose of Rystiggo®

Rystiggo® should be given at the same time each week. If you miss your dose at the usual time, please contact your doctor immediately for advice and to schedule another administration within the next 4 days.

The next dose should be given according to the original dosing schedule until the treatment cycle is completed.

Do not take a double dose to make up for the dose you missed.

If you are given too much Rystiggo®

Your doctor will ensure you are given the correct amount of Rystiggo®. If you think that you have been given too much Rystiggo®, contact your doctor.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while on Rystiggo®?

Remind any doctor, dentist or pharmacist you visit that you are using Rystiggo®.

Tell your doctor prior to a vaccination about your treatment with Rystiggo®.

Based on your doctor's instruction, administration of Rystiggo® is required to be done by a doctor or a nurse.

Call your doctor straight away if you:

- develop symptoms such as severe headache, fever, stiffness of the neck, nausea, vomiting and/or intolerance to bright light; because these could be symptoms of aseptic meningitis (non-bacterial inflammation of the membranes that surround the brain and spinal cord) or
- if you have an infection or symptoms of an infection.

Things you should not do:

- Use medicine if the expiration date on the packaging has passed,
- if the carton seals have been broken..

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Rystiggo® affects you.

Rystiggo® is not likely to affect your driving and use of machines.

Looking after your medicine

- Store in a refrigerator between 2°C to 8°C.
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- The Rystiggo® vial may be stored at room temperature (up to 25°C) for a single period of maximum 20 days with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 20 days or by the expiry date, whichever occurs first.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Discard after the expiry date.

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are mild and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Brain and nerves: Headache including migraine (without fever and/or neck stiffness) **Muscles and bones:** • Joint pain **Gut and digestion:** • Diarrhoea **Skin:** • Skin rash, sometimes with red bumps. • Painful skin rash with blisters in one part of the body. • Cold sores **Other common side effects:** • Fever • Nose and throat infections • Injection site reaction, including injection site rash, redness of the skin, inflammation, discomfort and infusion site pain.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Signs of aseptic meningitis (non-bacterial inflammation of the tissue covering the brain and spinal cord), such as: • Headache with nausea • vomiting, • stiff neck • fever, and/or • sensitivity to light. **Allergic reaction:** • Difficulty breathing or swallowing • low blood pressure, which can make you dizzy or light-headed • swelling of the face, lips, tongue or throat • severe itching of the skin, with a red rash or raised bumps.	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Rystiggo® contains

Active ingredient (main ingredient)	Rozanolixizumab
Other ingredients (Inactive ingredients)	Histidine, histidine hydrochloride monohydrate, proline, polysorbate 80 and water for injections

Do not take this medicine if you are allergic to or react to any of these ingredients.

What Rystiggo® looks like

Rystiggo® is a colourless to brownish-yellow, clear to slightly opalescent.

Each pack has a single 2 mL vial, Aust R 427684.

Who distributes Rystiggo®

UCB Pharma

A division of UCB Australia Pty Ltd

Phone: +613 9828 1800

Website: www.ucbpharma.com.au

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