**Package leaflet: Information for the patient**

**Rystiggo 140 mg/ml solution for injection**
rozanolixizumab

▼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 start using 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Rystiggo is and what it is used for

**What is Rystiggo**

Rystiggo contains the active substance rozanolixizumab. Rozanolixizumab is a monoclonal antibody (a type of protein) designed to recognise and attach to FcRn, a protein that keeps the immunoglobulin G (IgG) antibodies in the body for longer.

Rystiggo is used together with standard therapy in adults to treat generalised myasthenia gravis (gMG), an autoimmune disease that causes muscle weakness which can affect multiple muscle groups throughout the body. The condition can also lead to shortness of breath, extreme fatigue and difficulties swallowing. Rystiggo is used in adults with gMG that produces IgG autoantibodies against acetylcholine receptors or muscle-specific kinase.

In generalised myasthenia gravis (gMG), these IgG autoantibodies (proteins of the immune system that attack parts of a person's own body) attack and damage proteins that are involved in communication between nerves and muscle, called acetylcholine receptors or muscle-specific kinase. By attaching to FcRn, Rystiggo reduces the level of IgG antibodies, including IgG autoantibodies, thereby helping to improve symptom of the disease.

## 2. What you need to know before you use Rystiggo

**Do not use Rystiggo**

- If you are allergic to rozanolixizumab or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using this medicine if any of the following applies to you:

Myasthenic crisis
Your doctor may not prescribe this medicine if you are, or are likely to be, on a ventilator due to gMG muscle weakness (myasthenic crisis).

Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)
Aseptic meningitis has been observed in association with this medicine at a higher dose. Seek immediate medical attention if you develop symptoms of aseptic meningitis such as severe headache, fever, stiffness of the neck, nausea, vomiting and/or intolerance to bright light.

Infections
This medicine may reduce your natural resistance to infections. Before starting or during treatment with this medicine, inform your doctor if you have any symptoms of infection (feeling warm, fever, chills or shivering, cough, sore throat or fever blisters may be signs of an infection).

Hypersensitivity (allergic reactions)
This medicine contains a protein that can cause reactions such as rash, swelling or itching in some people. You will be monitored for signs of an infusion reaction during and for 15 minutes after treatment.

Immunisations (vaccinations)
Please inform your doctor if you have received a vaccine in the last 4 weeks, or if you plan to be vaccinated in the near future.

**Children and adolescents**

Do not give this medicine to children below the age of 18 years because the use of Rystiggo has not been studied in this age group.

**Other medicines and Rystiggo**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Taking Rystiggo with other medicines may decrease the effectiveness of those medicines, including therapeutic antibodies (such as rituximab) or subcutaneous or intravenous immunoglobulins. Other medicines, including subcutaneous or intravenous immunoglobulins, or interventions such as plasmapheresis (a process in which the liquid part of the blood, or plasma, is separated from blood that has been drawn from a person), may impair the effect of Rystiggo. Tell your doctor if you are taking or planning to take other medicines.

Tell your doctor about your treatment with Rystiggo before you have a vaccination. This medicine may impair the effect of vaccines. Vaccination with so-called live-attenuated or live vaccines is not recommended during treatment with Rystiggo.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

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.

It is not known whether this medicine passes into human milk. Your doctor will help you decide if you should breast-feed and use Rystiggo.

**Driving and using machines**
Rystiggo is not likely to affect your driving and use of machines.

**Rystiggo contains proline**
This medicine contains 29 mg of proline in each ml of medicine.
Proline may be harmful for patients with hyperprolinaemia, a rare genetic disorder in which an excess of the amino acid, proline, builds up in the body.
If you have hyperprolinaemia, tell your doctor and do not use this medicine unless your doctor has recommended it.

## 3. How to use Rystiggo

Treatment with Rystiggo will be initiated and supervised by a specialist physician experienced in the management of neuromuscular or neuro-inflammatory disorders.

**How much Rystiggo is given and for how long**

You will be given Rystiggo in cycles of 1 infusion per week for 6 weeks.
Your doctor will calculate the correct dose for you based on your weight:
- if you weigh at least 100 kg, the recommended dose is 840 mg per infusion (requiring 6 ml per administration)
- if you weigh from 70 kg to less than 100 kg, the recommended dose is 560 mg per infusion (requiring 4 ml per administration)
- if you weigh from 50 kg to less than 70 kg, the recommended dose is 420 mg per infusion (requiring 3 ml per administration)
- if you weigh from 35 kg to less than 50 kg, the recommended dose is 280 mg per infusion (requiring 2 ml per administration)

The frequency of treatment cycles varies for each patient and your doctor will consider if and when a new treatment cycle is appropriate for you.

Your doctor will advise you on how long you should be treated with this medicine.

**How Rystiggo is given**

Rystiggo will be given to you by a doctor or nurse.

You will be given this medicine as an infusion under the skin (subcutaneous use). It is usually injected into the lower part of the tummy, below the belly button. Injections should not be given into areas where the skin is tender, bruised, red or hard.

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

**If you receive more Rystiggo than you should**

If you suspect that you have been accidentally administered a higher dose of Rystiggo than prescribed, please contact your doctor for advice.

**If you forget or miss an appointment to receive Rystiggo**

If you miss a dose, please contact your doctor immediately for advice and to schedule another appointment to receive Rystiggo within the next 4 days. Thereafter, the next dose should be given according to the original dosing schedule until the treatment cycle is completed.

**If you stop using Rystiggo**

Do not stop using this medicine without talking to your doctor first. Interrupting or stopping treatment with Rystiggo may cause your symptoms of generalised myasthenia gravis to come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The below side effects, presented in order of decreasing frequency, have been observed with Rystiggo:

**Very common:** may affect more than 1 in 10 people
- Headache (including migraine)
- Diarrhoea
- Fever (pyrexia)

**Common:** may affect up to 1 in 10 people
- Rapid swelling under the skin in areas such as the face, throat, arms and legs (angioedema)
- Joint pain (arthralgia)
- Skin rash, sometimes with red bumps (rash papular)
- Injection site reaction including injection site rash, redness of the skin (erythema), inflammation, discomfort, and infusion site pain

**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:

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 Rystiggo

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 vial label and outer carton after EXP. The expiry date refers to the last day of that month.

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

Keep the vial in the outer carton in order to protect from light.

Each vial of solution for injection must be used only once (single use). Any unused product or waste material should be disposed of in accordance with local requirements.

Do not use this medicine if you notice that the liquid looks cloudy, contains foreign particles, or has changed colour.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Rystiggo contains

- The **active substance** is rozanolixizumab. Each ml of solution contains 140 mg of rozanolixizumab. Each vial of 2 ml contains 280 mg rozanolixizumab.
- The **other ingredients** are: histidine, histidine hydrochloride monohydrate, proline, polysorbate 80, and water for injections. See section 2 Rystiggo contains proline.

### What Rystiggo looks like and contents of the pack

Rystiggo is a solution for injection. Each carton contains 1 vial of 2 ml solution for injection. The solution is colourless to pale brownish-yellow, clear to slightly opalescent.
The devices used for administration should be procured separately.

**Marketing Authorisation Holder**
UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom

**Manufacturer**
UCB Pharma S.A., Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium

**This leaflet was last revised in November 2023**.

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The following information is intended for healthcare professionals only:

**Instructions for Use for Healthcare Professionals**
**Handling Rystiggo By Means of A Device-Assisted Infusion Technique**
**eg an Infusion Pump**

For subcutaneous use only.

The number of vials (2 ml per vial) to be used depends on the body weight of the patient. To administer the 280 mg dose to patients weighing ≥ 35 to < 50 kg, 2 ml are necessary. To administer the 420 mg dose to patients weighing ≥ 50 kg to < 70 kg, 3 ml are necessary. To administer the 560 mg dose to patients weighing ≥ 70 to < 100 kg, 4 ml are necessary. To administer the 840 mg dose to patients weighing ≥ 100 kg, 6 ml are necessary. See section 3.

The rozanolixizumab solution for injection can be administered using polypropylene syringes as well as infusion sets containing polyethylene (PE), low density polyethylene (LDPE), polyester, polyvinyl chloride (PVC without DEHP), polycarbonate (PC), fluorinated ethylene polypropylene (FEP),

urethane/acrylate, polyurethane, meta-acrylonitrile butadiene styrene (MABS), silicone or cyclohexanone. Do not use administration devices labelled as containing di(2-ethylhexyl)phthalate (DEHP).

Read ALL the instructions below before you administer Rystiggo.

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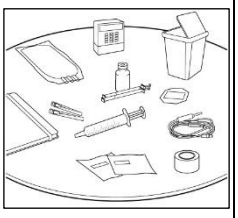
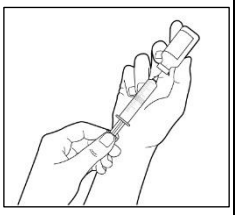
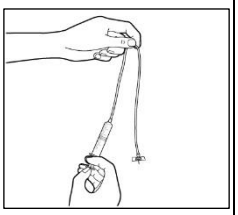
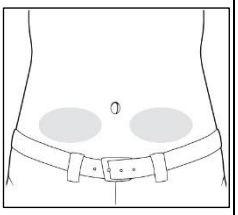
| **1** | **Remove Rystiggo from the box:**<br>• Allow vials to reach room temperature. This may take a minimum of 30 minutes up to 120 minutes. Do not use heating devices.<br>• Check each vial before using:<br>▪ Expiration date: Do not use beyond expiration date.<br>▪ Colour: The solution should be colourless to pale brownish-yellow, clear to slightly opalescent. Do not use the vial if the liquid looks cloudy, contains foreign particles, or has changed colour.<br>▪ Cap: Do not use if protective cap of the vial is missing or defective. |
| **2** | **Gather all items:**<br>• Collect all items for the infusion. In addition to the vial unit(s), collect the following, which are not supplied: syringe, syringe needle(s), alcohol wipe, infusion set, tape or transparent dressing, infusion pump and sharps container.<br>  |
| **3** | **Use aseptic technique when preparing and administering this product** |
| **4** | **Prepare Rystiggo for infusion**<br>  <br>• Use transfer needles to fill the syringe.<br>• Take the protective cap off the vial and clean the vial stopper with an alcohol wipe. Let dry.<br>• Extract the entire content of the vial into the syringe. A small amount will remain in the vial and should be discarded.<br>• For multiple vials, use a fresh needle and repeat previous steps.<br>• Remove the needle from the syringe and attach the infusion set to the syringe. |
| **5** | **Prepare the infusion**<br>  <br>• Follow instructions provided with the infusion pump to prepare the pump, and prime the infusion line. Administer immediately after priming the infusion set.<br>• Each vial contains excess volume (to allow priming of the infusion line); therefore, pre-set the pump to deliver the prescribed volume. For pumps that cannot be pre-set, after priming the infusion line, adjust the volume to be administered by expelling any excess volume. |
| **6** | **Prepare the infusion site**<br>  <br>• Choose an infusion area: lower right or lower left part of the abdomen, below the belly button. Never infuse into areas where the skin is tender, bruised, red or hard. Avoid infusing into scars or stretch marks.<br>• Clean the infusion site using alcohol wipe. Allow to dry. |

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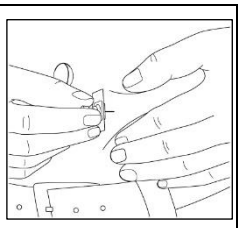
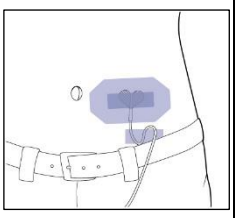
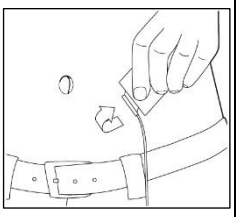
| **7** | **Insert the infusion set needle**<br>• Take an abdominal skinfold between two fingers.<br>• Insert the infusion set needle into the subcutaneous tissue.<br>  |
| **8** | **Secure the needle to the skin**<br>• If necessary, use tape or transparent dressing to hold the needle in place.<br>  |
| **9** | **Start infusion**<br>• Follow the manufacturer's instructions for using the pump. |
| **10** | **End infusion**<br>• When the infusion is complete, do not flush the infusion line as the volume of infusion has been adjusted taking into account the losses in the line.<br>• Remove needle from the infusion site.<br>  |
| **11** | **Clean up**<br>• Discard in a sharps container all items with remaining product i.e. partially used vials, infusion set and any administration supplies. |