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. 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 one dose a week for 6 weeks. A doctor or nurse will administer Rystiggo® to you via an infusion under the skin. Rystiggo® can be injected by you or a caregiver after receiving training from doctor or nurse. 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. • 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. • Do not give yourself Rystiggo® until you have been trained on how to do it.
Looking after your medicine	• Keep this medicine out of the sight and reach of children. • Store in a refrigerator between 2°C to 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®?
2. What should I know before I am given Rystiggo®?
3. What if I am taking other medicines?
4. How am I given Rystiggo®?
5. What should I know while on Rystiggo®?
6. Are there any side effects?
7. Product details

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:

- have an infection or any symptoms of an infection
- 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® can also be injected by yourself. You and your doctor or nurse will decide if, after training by a healthcare professional, you can inject this medicine yourself. Another person may also give your injections after they have been trained.

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)
From 35 to below 50 kg	280 mg	2 mL
50 kg to below 70 kg	420 mg	3 mL
70 kg to below 100 kg	560 mg	4 mL
100 kg or more	840 mg	6 mL

Each vial contains at least 0.4 mL of additional medicine. This extra volume is not part of your dose and is necessary to fill the infusion line.

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

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

Rystiggo® can also be injected by yourself. You and your doctor or nurse will decide if, after training by a healthcare professional, you can inject this medicine yourself.

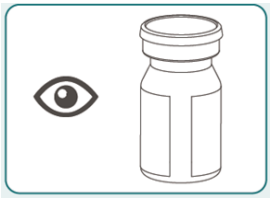
Another person may also give your injections after they have been trained. Do not give yourself or someone else Rystiggo® until you have been trained on how to do it.

If you or your caregiver inject Rystiggo®, you or your caregiver must carefully read and follow the Instructions for use below:

- If you are using an infusion pump (also known as a syringe pump) to give yourself Rystiggo®, please read the instructions provided by your doctor or nurse on how to set up the pump.
- If you are using a non-programmable pump, please refer to the manufacturer's instructions for use and your nurse's guidance on how to fill the infusion line and set the dose.

<u>Important information you need to know before giving yourself or someone else Rystiggo®.</u>

- For under the skin (subcutaneous) use only.
- Use each vial only once.
- Check your dose – you may need more than 1 vial to prepare your prescribed dose. If you do not have enough vial(s) for your prescribed dose, contact your doctor or nurse for next steps.
- Do not use Rystiggo® if the expiry date has passed.



- Do not use the vial if the liquid has particles you can see. The medicine should be colourless to pale brownish-yellow, clear to slightly opalescent (pearly white).

- **Do not** shake the vial.
- **Do not** use the vial if the protective cap is missing or broken. If any of the vials are broken or do not have a cap, report and return them to the pharmacy.



- Remove the box from the fridge before your infusion. For a more comfortable infusion, let the vial reach room temperature before you use this medicine. This may take 30 to 120 minutes. Do not warm in any other way.

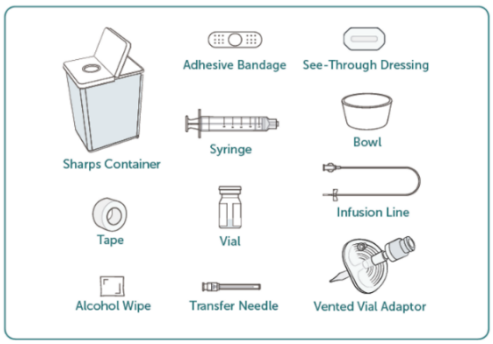


1. <u>Get ready</u>

Step 1: Gather all the supplies you will need on a clean and flat work surface:

- **Included** in the Rystiggo® box:
  - Rystiggo® vial.
  - Rystiggo® package leaflet.
  - Check your dose – you may need more than 1 vial to prepare your prescribed dose.
- **Not included** in the Rystiggo® box:
  - Syringe (5 -10 ml depending on your prescribed dose).
  - Transfer needle with 18G needle or larger diameter or a vented vial adaptor.
  - Infusion line with a 26G needle or larger diameter. The infusion line should be 61 cm in length or shorter.
  - Alcohol wipes.
  - Tape or see-through dressing.
  - Adhesive bandage.
  - Sharps container.

- Bowl or paper towel to collect extra liquid when filling the infusion line.
- Syringe pump – if you are using a pump.



The supplies above are for illustration only. Your specific supplies may look different.

Step 2: Clean your work surface and hands

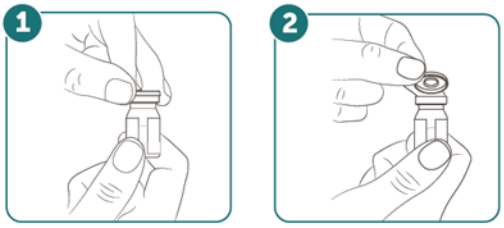
- Clean your work surface with disinfectant and wash your hands carefully with soap and water or use a hand sanitiser. Dry them on a clean towel.

2. <u>Prepare the vial(s) and syringe</u>

Check your dose – you may need more than 1 vial to prepare your prescribed dose.

Step 3: Remove the protective cap from the vial(s)

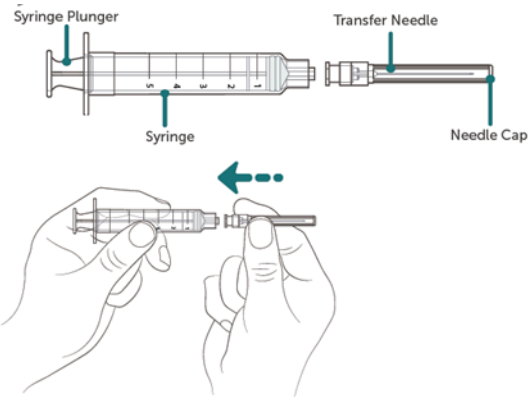
- Take the protective cap off the vial(s) by holding the edge and lifting upwards.
- Clean the rubber stopper with an alcohol wipe. Allow to air-dry.
- Leave the aluminium shield in place.
- Check your dose - if you need more than one vial to prepare your prescribed dose, remove all the caps and clean the stoppers.



If you are using a vented vial adaptor instead of a transfer needle, you can skip directly to Step 7.

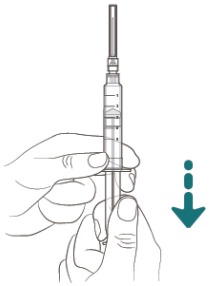
Step 4: Attach the transfer needle to the syringe

- Remove the plastic covers from the syringe and transfer needle. Do not touch the tip of the syringe or the base of the needle to avoid germs.
- With the needle cap still on, gently push or twist the transfer needle onto the syringe until it is firmly connected.



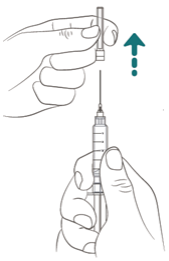
Step 5: Draw air into the syringe

- Slowly pull down on the syringe plunger to draw air into the syringe.
- Fill the syringe with about the same amount of air as the amount of medicine in the vial.
- Keep the needle cap on while you are doing this.



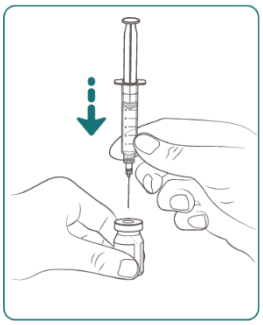
Step 6: Remove the needle cap from the transfer needle

- Hold the syringe with one hand.
- With your other hand, hold the transfer needle cap and pull it straight off the needle.
- Place the cap on the table to throw away later.
- Do not touch the needle tip.
- Do not let the needle tip touch anything after you remove the cap.

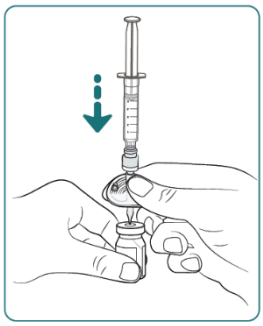


Step 7: Insert the transfer needle or vented vial adaptor directly into the vial

- Place the vial on the table and insert the transfer needle or vented vial adaptor straight through the rubber stopper.



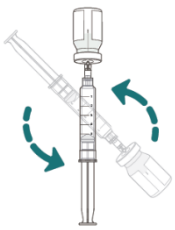
Using transfer needle



Using vented vial adaptor

Step 8: Turn the vial and syringe

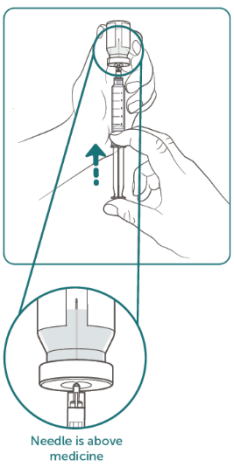
- Now turn the vial and syringe upside-down.
- Keep the transfer needle or vented vial adaptor inside the vial.



If you are using a vented vial adaptor, you can skip directly to Step 11.

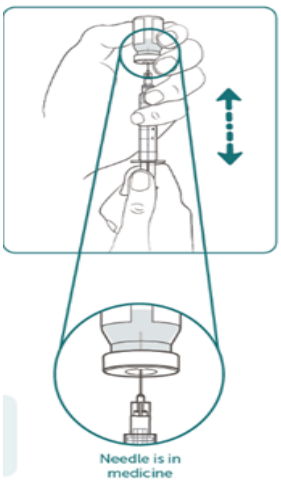
Step 9: Push air from the syringe into the vial

- Check that the transfer needle now points upwards and make sure the needle tip is in the space above the medicine.
- Slowly push the syringe plunger upwards to push all the air from the syringe into the vial. Keep your thumb pressed on the syringe plunger the whole time – so you do not let air into the syringe.
- Keep the needle tip in the space above the medicine the whole time.
- Do not push air into the medicine as this can create bubbles.



Step 10: Get ready to fill the syringe

- Keep your thumb pushed on the syringe plunger. With your other hand, pull the vial slowly and carefully upwards so the needle tip is fully covered by the liquid medicine.



Step 11: Fill the syringe with as much medicine as possible

Check your dose – you may need more than 1 vial to prepare your prescribed dose.

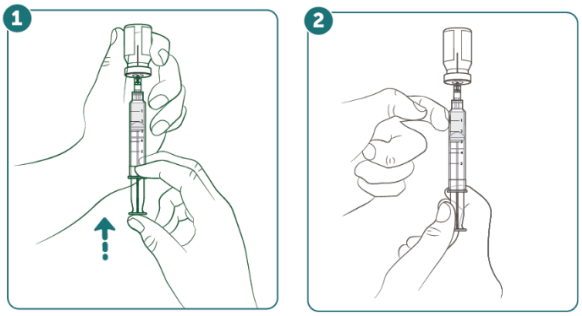
- Now slowly pull the syringe plunger down and fill the syringe with medicine as much medicine as possible.
- If you are using a transfer needle to fill the syringe, do the following:
    - Keep pulling the vial slowly and carefully upwards to keep the tip of the needle fully covered by the liquid.
    - Adjust the needle tip to keep it in the liquid. This will help you to take as much medicine out of the vial(s) as possible.
- You should now have more medicine in the syringe than your prescribed dose. This is because each vial contains at least 0.4 mL of additional medicine. This extra volume is not part of your dose and is necessary to fill the infusion line, in step 16.

There will also be a very small amount of the medicine that you cannot take out of the vial. You will throw this away with the vial later.

If you are using a vented vial adaptor, detach the syringe from the vented vial adaptor. Leave the vented vial adaptor in the vial. You can throw this away at the end of the infusion. You can now skip directly to Step 14.

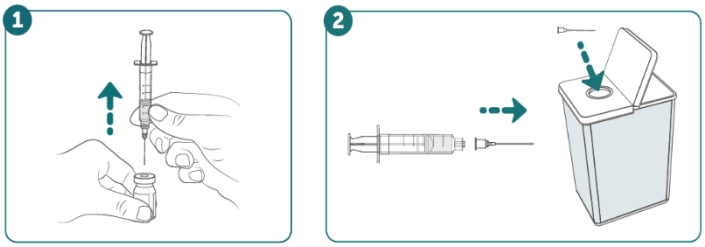
Step 12: Remove air from the syringe

- If there is any space between the liquid in the syringe and the top of the syringe, slowly push the plunger to push air back into the vial.
- If you see air bubbles in the syringe, you can remove them by tapping gently on the syringe with your index finger. Now slowly push the plunger to push air back into the vial.



Step 13: Remove the transfer needle from the vial and the syringe

- Turn the vial and syringe over and put the vial on the work surface.
- Remove the transfer needle and syringe from the vial by pulling straight up on the syringe.
- Remove the transfer needle from the syringe by pulling or twisting carefully on the base of the needle.
- Do not touch the needle. Do not put the needle cap back on.
- Throw the needle away in the sharps container.
- If you are using a vented vial adaptor instead of a needle, it is not necessary to remove the vented vial adaptor from the vial before throwing them away.



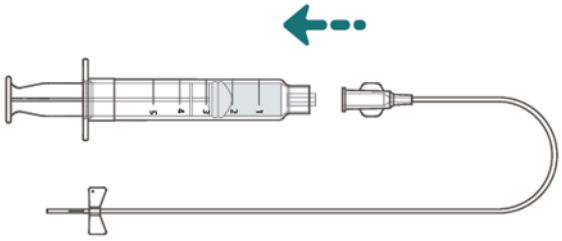
Step 14: Re-check your dose

If you need to use another vial to prepare your prescribed dose, repeat Steps 4-13 with the same syringe and a new transfer needle or vented vial adaptor to avoid contamination.

3. <u>Prepare for infusion</u>

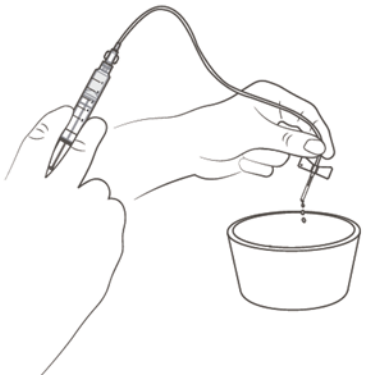
Step 15: Attach the infusion line onto the syringe

- Place the syringe on the clean work surface while you are preparing the infusion line.
- Remove the infusion line from the protective pouch.
- Remove the cap from the end of the infusion line by twisting it off. Place the cap on the work surface to throw away later.
- Attach the infusion line onto the syringe until firmly connected. Do not touch the tip of the syringe or the base of the infusion line to avoid germs.
- Do not remove the needle cap from the infusion line needle.



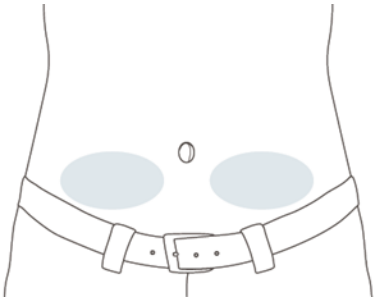
Step 16: Fill the infusion line with medicine

- Make sure you have a bowl or paper towel in front of you – you can use it to collect any medicine from the infusion line that is not needed.
- Keep the cap on the infusion line needle and hold it over the bowl.
- Gently push the syringe plunger until the
- amount of liquid left in the syringe is your prescribed dose.
- Your infusion line will also be filled.
- If you are using a syringe pump, please read the manufacturer's instructions on how to set up and operate the pump and fill the infusion line.



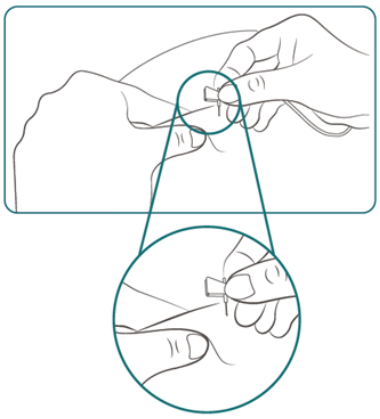
Step 17: Choose and prepare the infusion site

- Choose an infusion site to the lower left or lower right side of the tummy (abdomen), below the level of the belly button.
  - Do not use an area of skin which:
    - is tender, bruised, red or hard
    - has scars or stretch marks.
- Prepare the infusion site:
  - Clean the infusion area with an alcohol wipe and allow it to air-dry.



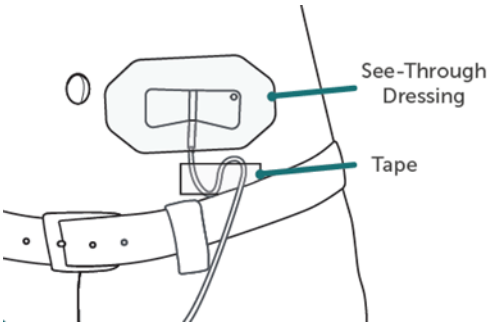
Step 18: Insert the infusion line needle

- Carefully remove the needle cap from the infusion line needle.
- Fold the butterfly wings together and hold them with your thumb and index finger of one hand.
- With your other hand, pinch the skin between 2 fingers to make a fold.
- Push the needle into the middle of the skin fold until the needle is under the skin.
- The needle should go in easily. If it is difficult, you can pull the needle out slightly.
- You may be using an infusion line without a butterfly-type needle at the end. Your nurse or doctor will explain to you how to insert the needle.



Step 19: Secure the infusion line needle

- Use a see-through dressing to hold the needle in place. Some infusion sets have a built-in adhesive.
- You can use tape to hold the infusion line on your skin.



4. Infuse and finish

Step 20: Start the infusion

Follow the instructions for the infusion method you are using:

- **Manual push**
    - Sit back comfortably and push firmly on the syringe plunger to infuse the medicine.
    - You should infuse the medicine at a speed that feels comfortable to you. Keep pushing until there is no more medicine left in the syringe.
    - Before and during the infusion, make sure that the infusion line does not twist or bend. If this happens, the flow of medicine can be interrupted. In this case, correct the bend in the infusion line and try again.
- If it feels uncomfortable or if any of the medicine flows back into the infusion line, you can push more slowly.

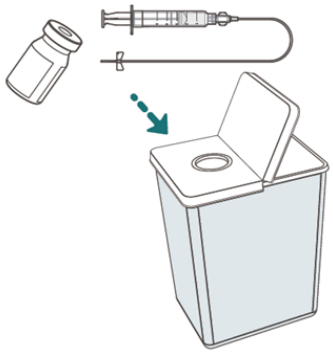
- **Syringe pump** - before you use a syringe pump, make sure that you understand the following:
    - How to set up your syringe pump (set an infusion rate of up to 20 ml per hour).
    - How to set the occlusion alarm to maximum setting.
    - How to start the syringe pump.
    - What the various syringe pump sounds and alarms mean and how to manage them.
    - How to stop the syringe pump.

- When you are ready to infuse:
    - Place the syringe in the syringe holder and start the pump by following the pump instructions.
    - Sit back comfortably while the pump gives you the medicine.
    - Before and during the infusion, make sure that the infusion line does not twist or bend. If this happens, the flow of medicine can be interrupted. In this case, correct the bend in the infusion line and try again.
    - Once it has finished, stop the pump by following the pump instructions.
    - Take the syringe out of the syringe pump.

Note: There will be some medicine left in the infusion line. This is normal and you can throw it away in the sharps container.

Step 21: Finish the infusion and clean up

- After you finish the infusion, do not try to take the dressing off the needle. Remove them both from your skin together and throw them away with the syringe in the sharps container.
- There may be a drop or two of liquid at the infusion site after you take out the needle. This is normal.
- Throw away any used vial(s) and leftover medicine into the sharps container.
- Cover the infusion site with a clean dressing, such as an adhesive bandage.
- Throw away any other used supplies in your household waste.



Always keep the sharps container out of the sight and reach of children.

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, Rystiggo® may be given within next 4 days of your missed dose.

If you miss your dose at the usual time and a doctor or nurse is giving you Rystiggo® schedule another appointment within the next 4 days.

Ensure the next dose is given according to the original dosing schedule until the treatment cycle is completed.

Please contact your doctor for further advice.

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®?

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®.
- 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).
- if you have an infection or symptoms of an infection.

Things you should not do

- Do not use this medicine if the expiration date on the packaging has passed.
- Do not use this medicine 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 or 20 days after removing the medicine from the refrigerator, whichever occurs first.

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 minor 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:	**Speak to your doctor if you have any of these less**

Less serious side effects	What to do
• 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.	**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 or react to any of these ingredients.

What Rystiggo® looks like

Rystiggo® is a colourless to brownish-yellow, clear to slightly opalescent solution and is available the following sizes:

- 2 mL vial, AUST R 427684
- 3 mL vial, AUST R 523777
- 4 mL vial, AUST R 523778

Who distributes Rystiggo®

UCB Pharma

A division of UCB Australia Pty Ltd

Phone: +613 9828 1800

Website: www.ucbpharma.com.au

E-mail: ucbcares.au@ucb.com

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