

RYSTIGGO[®] ▼

rozanolixizumab

Intended for HCPs only

HCP infusion guide

INDICATION:

RYSTIGGO[®] is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.¹

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Prescribing information can be found [here](#), and adverse event reporting information is at the end of this guide.

This guide has been developed by UCB Pharma.

This is a guide for the administration of RYSTIGGO® (rozanolixizumab) injection for subcutaneous (SC) infusion. RYSTIGGO® can be administered either by a healthcare professional (HCP) or by a patient/caregiver following proper training.

It includes:

- About generalised myasthenia gravis (gMG)
- Indication, dosing and administration options
- Infusion pump criteria
- What you will need for RYSTIGGO® administration
- Frequently asked questions (FAQs)

This guide does not replace the RYSTIGGO® SmPC. This guide does not include all the information needed to use RYSTIGGO® safely and effectively. Please refer to the full SmPC before administering RYSTIGGO®.

ABOUT GENERALISED MYASTHENIA GRAVIS (gMG) AND PEOPLE WITH gMG

- gMG is an autoimmune disease.^{2,3} Autoantibodies against acetylcholine receptors (AChR) are present in approximately 85% of people living with gMG.² In these people, the development of pathogenic autoantibodies activates the complement cascade, which causes MAC formation and ultimately the destruction of the neuromuscular junction (NMJ) and inhibition of neuromuscular signals.⁴ AChR autoantibodies can also cause cross-linking of adjacent AChRs, increasing their rate of degradation and inhibiting neuromuscular signals in the absence of complement attack.² In a minority of patients, however, the pathogenic autoantibodies instead bind to muscle-specific kinase (MuSK), which is crucial for the development and maintenance of AChR clusters at the NMJ.²
- Common symptoms include fluctuating muscle weakness and fatigability of voluntary muscles including the ocular muscles, the masticatory, facial, pharyngeal and laryngeal muscles, and the respiratory and proximal limb muscles.⁵
- Myasthenia Gravis (MG) can be classified as ocular MG or gMG. Individuals may present with ocular symptoms first but, in 80–85% of cases, progress to gMG within 3 years and display symptoms in other muscle groups.^{5,6}
- A severe, acute exacerbation can occur – called a myasthenic crisis, resulting in respiratory failure, which can be fatal.⁷

DOSING

The recommended dose of RYSTIGGO® for adult patients with gMG is based on body weight as summarised in the table below:¹

Body weight	≥35 to <50 kg	≥50 to <70 kg	≥70 to <100 kg	≥100 kg
Weekly dose (mg)	280 mg	420 mg	560 mg	840 mg
Weekly dose (ml)	2 ml*	3 ml*	4 ml*	6 ml*

*One ml of solution for injection contains 140 mg of rozanolixizumab. Each vial contains excess volume for priming of the infusion line¹.

ADMINISTRATION OPTIONS

RYSTIGGO® is administered via a syringe, infusion line and needle into the patient's subcutaneous tissue. Once prepared, the administration can be driven in two ways:

1. By an infusion pump (also known as a syringe pump)
2. By manual push, where the syringe plunger is pushed by hand

IMPORTANT FOUNDATIONAL CONCEPTS TO CONSIDER

1. Resistance in the infusion system and tissues

To deliver volumes of liquid subcutaneously by either manual push or syringe pump, the administration pressure has to overcome friction/resistance in the syringe and infusion set, as well as the tissue resistance pressure.⁸ Hence, resistance is usually significantly higher during SC infusions vs intravenous (IV) infusions.

2. Occlusion pressure allowance/tolerance

Occlusion is the interruption of infusion due to a blockage, momentary closure or obstruction of the passageway.⁹ Occlusions can occur when using either syringe pump or manual push methods of administration. When administering via manual push, an occlusion can occur if the line twists or bends. In this case, the bend or twist can be corrected and the infusion can re-start.¹⁰ When administering using a syringe pump, an occlusion alarm can also be triggered by the pump itself. Therefore, it is important to consider the occlusion alarm settings on the pump.^{9,11}

3. Occlusion pressure alarm settings

SC infusions require higher pressure⁸ and a higher occlusion alarm threshold than IV infusions. If using a syringe pump which has not been specifically designed for SC infusions, it is necessary to have the occlusions pressure alarm set to maximum¹ before an SC infusion to avoid interrupting drug delivery because of false alarms.

4. Flow rate

Most syringe pumps can be programmed to deliver a specific flow rate, i.e., a specific volume of liquid within a specified time.¹¹ However, not all pumps have the same minimum flow rate, so it is important to select a pump that meets the flow rate requirements of RYSTIGGO®. RYSTIGGO® - when using a syringe pump - should be administered at a maximum flow rate of 20 ml/hour.¹

5. Volume to infuse

A suitable pump needs to be capable of delivering the required volume of liquid for the specified dose.¹¹ A RYSTIGGO® infusion is a low-volume infusion, with a volume as low as 2 ml.¹ Not all pumps are able to infuse such a low volume, so it is important to check the minimum infusion volume capability of a pump to ensure it is suitable.

This checklist provides information to assist in the administration of a RYSTIGGO® subcutaneous (SC) infusion.

Always refer to the Instructions for Use and the Prescribing Information before administering RYSTIGGO®. Follow the manufacturer's instructions for preparing the pump.

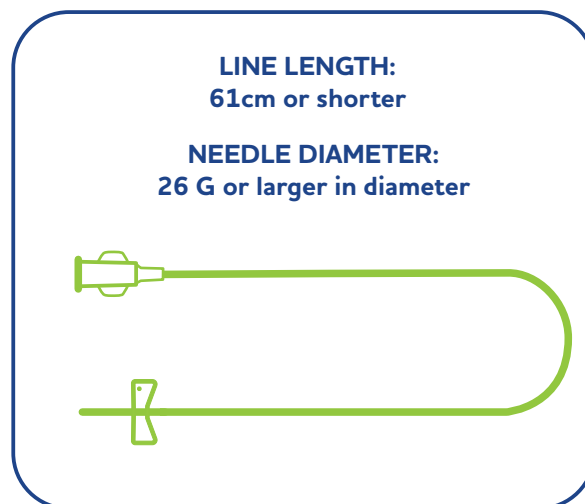
BEFORE ADMINISTERING RYSTIGGO®:

If a syringe pump is your preferred method of administration, choose and program an appropriate syringe pump according to the device manufacturer's instructions:^{1,10}

- The syringe pump needs to be able to deliver a minimum volume as low as 2 ml
- Constant flow rate should be set to maximum 20 ml/hour
- The occlusion pressure alarm must be set to its maximum pressure setting
- It is recommended to use a syringe pump where administered volume can be pre-set as each vial contains excess volume for priming of the infusion line.

Whether infusing by either manual push or syringe pump, ensure that you choose an appropriate infusion set:¹

- The infusion line should be 61 cm in length or shorter
- Use a needle that is 26 G or larger in diameter



ADMINISTRATION STEPS

RYSTIGGO® can be administered either by an HCP or by a patient/caregiver following proper training.

This section provides an overview of the **steps** for the **HCP administration of RYSTIGGO® only**. You can provide your patients with the '**RYSTIGGO patient infusion guide**' for more detailed steps of administration and useful tips to consider.

The following sections are:

- **Before the patient arrives**
- **When the patient arrives**
- **Prepare for the infusion**
- **Perform the infusion**
- **After the infusion**

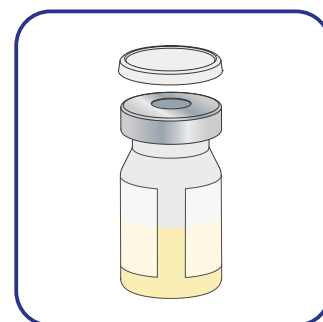


Read ALL the instructions below before you administer RYSTIGGO®.

BEFORE THE PATIENT ARRIVES

1

- Remove required number of vials from the fridge¹
- Allow vials to reach room temperature. This may take a minimum of 30 minutes up to 120 minutes. Do not use heating devices. If the vials are stored at room temperature, they can be used immediately¹
- Check each vial for:
 - **Date** – do not use a vial beyond its expiry date¹
 - **Colour** – The solution should be colourless to pale brownish-yellow, clear to slightly opalescent. Do not use if it has changed colour¹
 - **Particles and cloudiness** – do not use if the liquid contains foreign particles or is cloudy¹
 - **Protective cap** – do not use if the cap of the vial is missing or defective¹

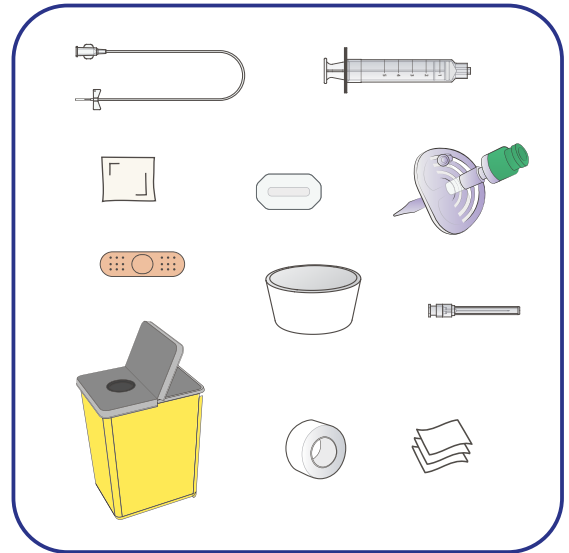


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- Gather all equipment including¹:
 - Infusion line with a 26G needle or larger diameter. The infusion line should be 61 cm in length or shorter
 - Transfer needle (18G or larger diameter) or a vented vial adaptor (preferably bell shaped)
 - Syringe (5 -10 ml depending on dose)
 - Alcohol wipes

- Tape or transparent dressing
- Bowl or paper towel to collect extra liquid when priming the infusion line
- Adhesive bandage
- Sharps container
- Compatible syringe pump if this is the chosen method of administration

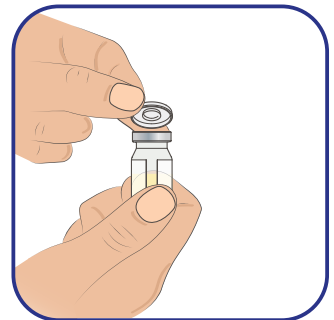
Please note for both methods of administration, each vial contains excess volume for priming of the infusion line. For those choosing to use a syringe pump, it is recommended to choose a model where the administered volume can be pre-set¹



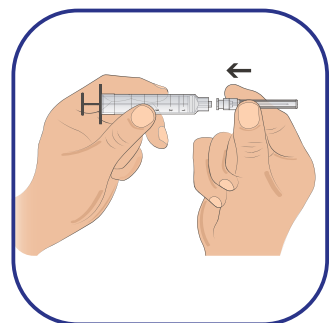
WHEN THE PATIENT ARRIVES

- 3 ■ Check patient details and explain the procedure

- 4 ■ Thoroughly wash and dry hands¹⁰
- Disinfect and prepare your work surface¹⁰
- Take the protective cap off the vial by holding the edge and lifting upwards¹⁰
- Clean the vial stopper with an alcohol wipe and let it dry¹⁰
- Leave the aluminium shield in place¹⁰
- Lay out all items required for the infusion¹⁰



- 5 ■ Attach the transfer needle to the syringe¹⁰
- Alternatively, if using a vented vial adaptor, insert the vial adaptor straight through the rubber stopper and attach the syringe to the vented vial adaptor¹⁰
- Extract the entire content of the vial into the syringe. A small amount will remain in the vial and should be discarded¹
- Each vial contains excess volume to allow priming of the infusion line¹
- When using multiple vials, use a fresh needle or vented vial adaptor and repeat previous steps¹



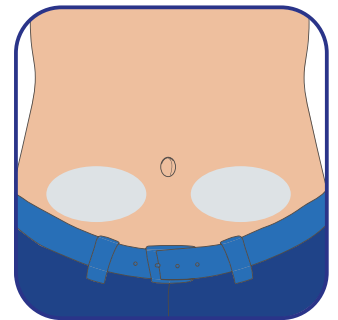
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- Remove the needle from the syringe and attach the infusion set¹
- Prime the infusion set to eliminate remaining air¹⁰
- Administer immediately after priming the infusion set¹
- If a syringe pump is your chosen method of administration, set it up according to the device manufacturer's instructions¹⁰
- Ensure occlusion pressure alarm is set to the maximum setting¹
- If using a non-programmable pump or the manual push method, the volume in the syringe should be adjusted to the prescribed dose prior to administration¹⁰



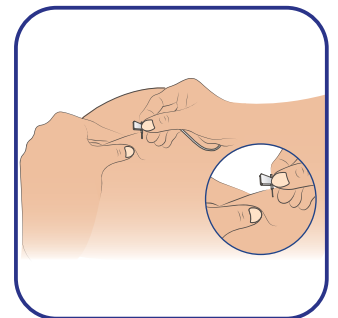
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- Select an area on the lower left or right side of the patient's abdomen, below the belly button. Never infuse into areas where the skin is tender, bruised, red or hard. Avoid infusing into scars or stretch marks¹
- Clean the infusion site using an alcohol wipe and let it dry¹



8

- Using two fingers, pinch together the skin around the infusion site and insert the needle¹⁰
- Secure the needle to the skin using tape or transparent dressing¹



Please follow either step 9a (manual push) or 9b (syringe pump) depending on your preferred method of administration.

9a

Administer infusion via manual push:^{1,10}

- Push firmly on the syringe plunger to infuse the medicine at a comfortable speed for the patient and continue until the syringe is empty
- In clinical trials, infusion times ranged from 1 to 30 minutes, with a median time of 5 minutes
- Monitor the patient for signs of an infusion reaction
- Do not flush the infusion line as the volume of infusion has been adjusted taking into account the losses in the line

9b

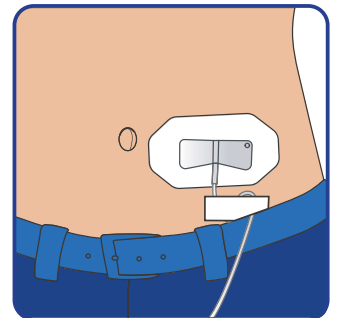
Administer infusion via a syringe pump:^{1,10}

- Start the syringe pump according to the device manufacturer's instructions
- Monitor the patient for signs of an infusion reaction
- Once the infusion is complete, switch off the syringe pump according to the manufacturer's instructions
- Do not flush the infusion line as the volume of infusion has been adjusted taking into account the losses in the line

AFTER THE INFUSION

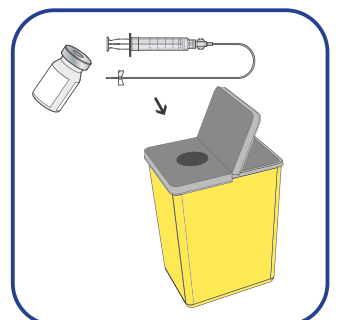
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- Remove the dressing/tape, needle and infusion line¹⁰



11

- Discard the needle, infusion line and all items with remaining product in a sharps container, i.e., needles, used vials, infusion set and any administration supplies¹⁰



12

- Check the infusion site for any reactions, e.g., rash, redness or swelling
- Apply a dressing to the infusion site
- Make sure the patient is feeling well and check for adverse reactions
- Make sure they have the correct contact details should any adverse reactions occur



- Patients should be monitored during treatment with RYSTIGGO® and for 15 minutes after the administration is complete for clinical signs and symptoms of hypersensitivity reactions¹

It may be useful to encourage your patients to track their symptoms in a diary. This provides a helpful way to record their infusion appointments and how their symptoms may change over time. It may also provide useful information to help you manage their condition and treatment.

References:

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4. Howard JF. Ann N Y Acad Sci. 2018;1412:113-28.
5. Juel VC, Massey JM. Orphanet J Rare Dis. 2007;2:44.
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7. Wendell LC, Levine JM. Neurohospitalist. 2011;1:16-22.
8. Patte C, et al. Diabetes Technol Ther. 2013;15(4):289-94.
9. Medical Devices Agency, NHS Scotland, UK. Adult medical emergency handbook, Appendix 3 - General principles of good practice: infusion devices. 2001; Appendix 3 - General Principles of Good Practice: Infusion Devices (scot.nhs.uk). [Accessed April 2026].
10. RYSTIGGO® (rozanolixizumab). Package leaflet: Information for the patient.
11. Zhang P, et al. J Biomed Sci Eng. 2009;2(6):431-34.

DO YOU HAVE ANY QUESTIONS ABOUT RYSTIGGO?

Get in touch with a UCB colleague.

Email the team

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd at ucbcares.uk@ucb.com or 0800 2793177



Inspired by **patients.**
Driven by **science.**

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