RYSTIGGO®
rozanolixizumab

Subcutaneous infusion administration handbook

RYSTIGGO® (rozanolixizumab)

Intended for HCPs only

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]

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

This handbook is designed as a comprehensive reference material for the administration of RYSTIGGO injection for SC infusion by a HCP.

It includes:

- About gMG
- Indication and dosing
- Syringe pump criteria
- Administration steps
- Frequently asked questions

This guide does not replace the RYSTIGGO Approved Product Information or Instructions for Use. This guide does not include all the information needed to use RYSTIGGO safely and effectively. Please refer to the full Product Information and Instructions for Use before administering RYSTIGGO.

Scan the QR code to watch the RYSTIGGO Dosing and Administration Video.

About gMG and people with gMG

- gMG is a well-characterised autoimmune disease.[2,3] Autoantibodies against AChR and MuSK are present in 85% and 1–10% of people living with gMG, respectively.[3,4] The development of pathogenic autoantibodies against AChR activates the complement cascade, which causes MAC formation and ultimately the destruction of the NMJ and inhibition of neuromuscular signals[4]
- Common symptoms include fluctuating 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]
- MG can be classified as ocular MG or gMG.[5] Individuals may present with ocular symptoms first but 80%–90% of cases progress to gMG within 2 years and display symptoms in other muscle groups[5–7]
- A severe, acute exacerbation called myasthenia crisis can occur, resulting in respiratory failure, which can be fatal[8]

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]

Dosing

The RYSTIGGO dose is determined by body weight as summarised in the table below:[1,9]

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
Number of vials to be used^	1	2	2	3

RYSTIGGO is administered for up to 18 minutes based on weight dependent dosing.[1]

^Each vial contains excess volume for priming of the infusion line. Each ml of solution for injection contains 140 mg of RYSTIGGO. One 2 ml vial contains 280 mg of RYSTIGGO.[1]

Supplies for the infusion[9]

- ✔ Required number of vials of RYSTIGGO (2 ml each)
- ✔ Syringe
- ✔ Syringe needles
- ✔ Transfer needle
- ✔ Sharps container
- ✔ Alcohol wipes
- ✔ Infusion set (including a thin infusion line that is 61 cm or shorter, and a needle of 26 G or larger)
- ✔ Tape or transparent dressing
- ✔ Compatible syringe pump

Important aspects to consider for syringe pump and ancillaries selection

1. Resistance in the infusion system and tissues

To deliver volumes of liquid subcutaneously, a syringe pump has to overcome friction/resistance in the syringe and infusion set, as well as the tissue resistance pressure.[10] Hence, resistance is usually significantly higher during SC infusions vs IV infusions.

2. Occlusion pressure allowance/tolerance for syringe pumps

Occlusion is the interruption of infusion due to a blockage, momentary closure or obstruction of the passageway.[11] Pumps usually have an occlusion pressure alarm – a safety feature that triggers when the pressure reaches a pre-set maximum.[11,12]

3. Occlusion pressure alarm settings

SC infusions require high pressure and a higher occlusion alarm threshold than IV infusions. Pumps that can be used for both SC and IV infusions must have the occlusion pressure alarm set to maximum before a SC infusion to avoid interrupting drug delivery because of false alarms.

4. Flow rate

Most syringe pumps can be set to a flow rate that will deliver a specific volume of liquid within a specified time.[12] 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 the medication and to adjust the pump settings accordingly.

5. Volume to infuse

A suitable pump needs to be capable of delivering the required volume of liquid for the specified dose.[12] A RYSTIGGO infusion is a low-volume infusion, delivered in 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 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:

Choose and set an appropriate syringe pump:[1,9]

- 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

Choose an appropriate infusion set:[1,9]

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

It is recommended to use an syringe pump where administered volume can be pre-set as each vial contains excess volume for priming of the infusion line.[1,9]

Administration steps

This section provides an overview of the **steps** for HCP administration of RYSTIGGO.
It also includes some useful tips.

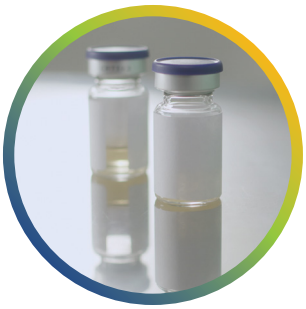
Read ALL the instructions below before you administer RYSTIGGO.

BEFORE THE PATIENT ARRIVES

1 Remove the required number of vials from the refrigerator[9]

- Allow vial(s) to reach room temperature. This may take a minimum of 30 minutes and up to 120 minutes. Keep the vial in the outer carton in order to protect from light.
- Do not use a heating device

2 Check the vial(s) for:[9]



- **Date** – do not use a vial beyond its expiry date
- **Colour** – the solution should be colourless to pale brownish-yellow, clear to slightly opalescent, do not use if it had changed colour
- **Particles and cloudiness** – do not use if the liquid contains foreign particles or looks cloudy
- **Intact protective cap** – do not use if the cap is missing or defective

WHEN THE PATIENT ARRIVES

3 **Check patient details and explain the procedure**

4 **Gather the supplies you will need for the infusion**[1,9]

- Required number of vials of RYSTIGGO (2 ml each)
- Syringe
- Syringe needles
- Transfer needle
- Sharps container
- Alcohol wipes
- Infusion set (including an infusion line that is 61 cm or shorter and a needle of 26 G or larger in diameter)
- Tape or transparent dressing
- Compatible syringe pump

It is recommended to use pumps where administered volume can be pre-set as each vial contains excess volume for priming of the infusion line[1,9]

5 **Once the vial(s) have reached room temperature and you are ready to start, disinfect your work surface and leave it to airdry**[9]

6 **Wash your hands thoroughly using soap and water or hand sanitiser and put on suitable clinical gloves**[9]

7 **Place the vial(s) on your work surface and remove the protective 'flip-off' plastic cap**[9]

DO NOT remove the rubber stopper

8 Wipe the rubber stopper with an alcohol wipe and allow it to dry[9]

- Extract the entire content of the vial into the syringe
- A small amount will remain in the vial and should be discarded
- For multiple vials, use a fresh needle and repeat previous steps
- Remove the needle from the syringe
- Dispose of the vials and needles appropriately in the sharps container

9 Attach the infusion set to the syringe[1,9]

- The infusion line should be 61 cm or shorter to help prevent occlusions and support the correct flow rate

10 Fill the infusion line[9]

- Prepare the infusion line immediately before use
- Prime the infusion set to eliminate remaining air

11 Set up the syringe pump[1,9]

- Refer to the manufacturer's instructions
- Ensure the occlusion pressure alarm is set to the maximum setting
- 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
- Check patient dosage to determine amount of excess volume to expel
- Set the infusion rate to up to 20 ml per hour

Weight-based dosing[1,9]

- **≥35 to <50 kg:** 280 mg (2 ml)
- **≥50 to <70 kg:** 420 mg (3 ml)
- **≥70 to <100 kg:** 560 mg (4 ml)
- **≥100 kg:** 840 mg (6 ml)

PERFORM THE INFUSION

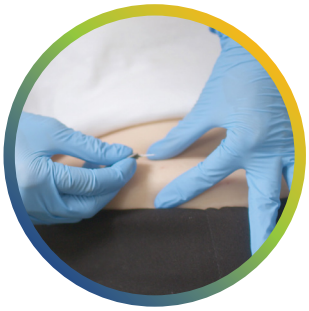
12 Make sure the patient is comfortable, either lying or sitting in a semi-reclined position

- The patient should be positioned in a way that allows easy access to the infusion site
- The patient should remain seated or lying comfortably in a semi-reclined position for the duration of the infusion

13 Clean the infusion site with an alcohol swab and allow to dry completely[1,9]

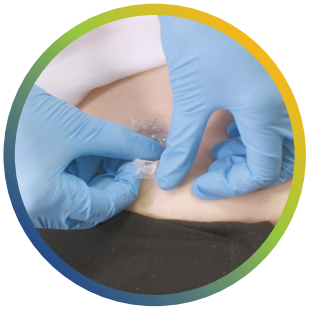
- Select an area for infusion on the patient's lower right or left part of the abdomen, below their belly button
- Never infuse into areas where the skin is tender, bruised, red or hard
- Avoid infusing into scars or stretch marks

14 Insert the needle[9]



- Remove the protective covering from the needle
- If you accidentally touch anything with the needle before inserting it, dispose of it in the sharps container, re-attach a new infusion line and re-prime the line
- Using two fingers, pinch together the skin around the infusion site and insert the needle at a 45 degree angle using a dart-like motion[13]

15 Secure the needle to the skin[9]



- Use tape or transparent dressing to hold the needle in place

16 Start the syringe pump[9]

- Make sure the infusion line is unobstructed
- Take note of the infusion details as per hospital guidelines including start time and flow rate
- Monitor the patient for signs of an infusion reaction, during and after treatment

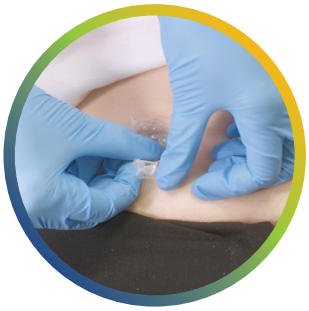
AFTER THE INFUSION

17 **Once the infusion is complete, switch off the syringe pump according to the manufacturer's instructions and record the infusion as per hospital guidelines[9]**

- Do not flush the infusion line as the volume of infusion has been adjusted taking into account the losses in the line

18 **Remove the transparent dressing/tape and the needle[9]**

- A drop or two of leakage might occur after the needle is removed



19 **Discard in a sharps container all items with remaining product i.e., partially used vials, infusion set and any administration supplies[1,9]**

20 **Check the infusion site for any reactions, e.g., rash, redness or swelling**

21 **Apply a dressing to the infusion site**

22 **Make sure the patient is feeling well and check for any adverse reactions**

- Check that the patient has the correct contact details and knows how to report any possible adverse reactions
- Confirm that they know when the next infusion will be
- Ask if they have any questions

If you have queries about how to administer RYSTIGGO, please contact your local UCB representative.

Frequently asked questions

The following are frequently asked questions about HCP administration of RYSTIGGO.

1. How is RYSTIGGO provided and stored?

RYSTIGGO should be stored in the refrigerator at 2–8°C. Do not freeze. Keep the vial in the outer carton in order to protect from light.[1]

2. How frequently is RYSTIGGO administered and what happens if a patient misses the scheduled infusion?

RYSTIGGO should be administered once per week for six weeks.[1] Subsequent treatment cycles are administered based on clinical evaluation.[1] If a scheduled infusion is missed, RYSTIGGO may be administered up to 4 days after the scheduled time point. Thereafter, the original dosing schedule should be resumed until the treatment cycle is completed.[1]

3. How long does the RYSTIGGO subcutaneous infusion take?

Time for infusion depends on the dosing volume and the flow rate. At a constant flow rate of 20 ml per hour, the infusion will take approximately 6 minutes for a 2 ml infusion (body weight: ≥35 to <50 kg), approximately 9 minutes for a 3 ml infusion (body weight: 50 to <70 kg), approximately 12 minutes for a 4 ml infusion (body weight: 70 to <100 kg) and approximately 18 minutes for a 6 ml infusion (body weight: ≥100 kg).[1,9]

4. What should the liquid look like?

RYSTIGGO is colourless to pale brownish-yellow, clear to slightly opalescent with no particles. If it has changed colour, is cloudy or contains foreign particles, do not use the vial.[1,9]

5. What should I do if I drop, break or contaminate the vial?

If this happens, please discard the affected vial into a sharps container and use a new vial for infusion.[9] If you receive a vial which is already broken, contaminated or is compromised in any way, please contact UCB via email ucbcares.au@ucb.com or phone 03 9828 1800 (option 3).

6. Should I keep any leftover solution for the next infusion?

No. At the end of each infusion, you must discard the vial and its remaining contents according to local guidelines.[9]

7. How can I prevent/reduce pain during the infusion?

Subcutaneous infusion is considered to be a relatively painless procedure. However, if the patient requires medication to prevent or reduce pain, this can be decided on an individual basis. Allowing the infusion site to dry after using an alcohol wipe and making sure there are no air bubbles in the liquid can both help to reduce the potential for a stinging sensation.

8. I have questions about RYSTIGGO that are not answered here or in the Product Information. Who can I go to for more information?

You should contact your local UCB representative.

Notes

Use this space to write down any notes or queries you may have for your local UCB representative.

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AChR, acetylcholine receptor; **gMG,** generalised myasthenia gravis; **HCP,** healthcare professional; **IV,** intravenous; **MAC,** membrane attack complex; **MG,** myasthenia gravis; **MuSK,** muscle-specific kinase; **NMJ,** neuromuscular junction; **SC,** subcutaneous.

References: 1. RYSTIGGO® (rozanolixizumab) Approved Product Information, 7 February 2025. **2.** Phillips WD, Vincent A. *F1000Res.* 2016;5:F1000 Faculty Rev-1513. **3.** Borges LS, Richman DP. *Front Immunol.* 2020;11:707. **4.** Howard JF. *Ann N Y Acad Sci.* 2018;1412:113–28. **5.** Juel VC, Massey JM. *Orphanet J Rare Dis.* 2007;2:44. **6.** Wang L, *et al. BMC Neurol.* 2017;17(1):77. **7.** Conti-Fine BM, *et al. J Clin Invest.* 2006;116(11):2843–54. **8.** Wendell LC, Levine JM. *Neurohospitalist.* 2011;1:16–22. **9.** RYSTIGGO® Approved Instructions for Use. 20 February 2025. **10.** Patte C, *et al. Diabetes Technol Ther.* 2013;15(4):289–94. **11.** 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 March 2024]. **12.** Zhang P, *et al. J Biomed Sci Eng.* 2009;2(6):431–34. **13.** Nursing Skills. 2nd edition. Chapter 18: Administration of Parenteral Medications. National Center for Biotechnology Information, National Library of Medicine. www.ncbi.nlm.nih.gov/books/NBK596739/. [Accessed March 2024].

PBS information: Not listed on the PBS for the treatment of generalised myasthenia gravis.

Before prescribing, please review full Product Information by scanning the QR code.
RYSTIGGO is currently unavailable in Australia.

▼This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at https://www.tga.gov.au/reporting-problems.

If you have a medical enquiry or wish to report an adverse event or product quality complaint, please contact UCB via email ucbcares.au@ucb.com or phone 03 9828 1800 (option 3).

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