RYSTIGGO (rozanolixizumab-noli) Injection for Subcutaneous Infusion

RYSTIGGO®
(rozanolixizumab-noli)
Injection For Subcutaneous Use
140 mg/mL

Visual administration guide

This guide is designed as a quick reference material and does not replace the prescribing information. Please refer to the full prescribing information before administering RYSTIGGO.[1]

INDICATION

RYSTIGGO (rozanolixizumab-noli) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infections: RYSTIGGO may increase the risk of infection. Delay administration of RYSTIGGO to patients with an active infection. Monitor for signs and symptoms of infection in patients treated with RYSTIGGO. If serious infection occurs, administer appropriate treatment and consider withholding RYSTIGGO until the infection has resolved.

Aseptic Meningitis: Serious events of aseptic meningitis have been reported. Monitor for symptoms; diagnostic workup and treatment should be initiated according to the standard of care.

Hypersensitivity Reactions: Angioedema and rash have occurred. If a hypersensitivity reaction occurs, discontinue RYSTIGGO infusion and institute appropriate therapy.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) in patients with gMG are headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea.

Please refer to the full Prescribing Information and visit www.RystiggoHCP.com.

BEFORE THE PATIENT ARRIVES

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- Remove required number of vials from storage[1]
- If they have been refrigerated, allow vials to reach room temperature. This may take approximately 30 minutes. Do not use heating devices. Keep the vial in the original carton to protect from light[1]
- Do not shake[1]

Check each vial for[1]:

- **Expiration date** – do not use beyond expiration date
- **Color** – The solution should be colorless to pale brownish-yellow, clear to slightly opalescent. Do not use if it has changed color
- **Particles and cloudiness** – do not use if the liquid contains foreign particles or is cloudy
- **Protective cap** – do not use if the protective cap of the vial is missing or defective

Collect all items for the infusion. In addition to the vial units, collect the following, which are not supplied[1]:

- Syringe
- Transfer needle/needles
- Alcohol wipe
- Infusion set
- Tape or transparent dressing
- Infusion pump
- Sharps container

Before administering RYSTIGGO, ensure that you refer to the infusion pump manufacturer's instructions for full preparation and administration information:

- Choose and set an appropriate infusion pump according to the device manufacturer's instructions
  - The infusion pump needs to be able to deliver a minimum volume as low as 3 ml[1]
  - Flow rate should be set to maximum 20 ml/hour[1]
  - The occlusion pressure alarm must be set to its maximum pressure setting[1]
- Choose an appropriate infusion set
  - The infusion line should be 61 cm or shorter[1]
  - Use a needle that is 26 G or larger diameter (lower gauge)[1]

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

RYSTIGGO should only be prepared and infused by a healthcare provider.[1] RYSTIGGO is for subcutaneous administration only using an infusion pump.[1] Use aseptic technique when preparing and administering this product.[1]

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WHEN THE PATIENT ARRIVES

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- Prepare a clean, flat, well-lit surface like a table
- Wash and dry your hands, thoroughly

PREPARE FOR THE INFUSION

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Transfer RYSTIGGO from vial to syringe[1]:

- Take the protective cap off the vial
- Clean the vial stopper with an alcohol wipe. Let the stopper dry
- Attach a sterile transfer needle to a sterile syringe
- Extract the entire content of the vial into the syringe. A small amount will remain in the vial and should be discarded
- If more than one vial is needed, use additional clean transfer needles and repeat previous steps
- Remove the needle from the syringe and attach the infusion set to the syringe
- Note: Infuse RYSTIGGO within 4 hours of puncturing the vial. Administer immediately after priming the infusion set

Prepare infusion pump and tubing[1]:

- Follow the manufacturer's instructions for preparing the infusion pump
- Prime (fill) the infusion set to eliminate remaining air. To prime the tubing, connect the syringe filled with RYSTIGGO to the infusion tubing and gently push on the syringe plunger to fill the tubing with RYSTIGGO
- 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
- Insert syringe filled with RYSTIGGO into the infusion pump

PERFORM THE INFUSION

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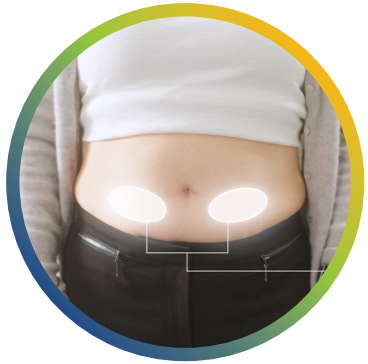

Prepare the infusion site[1]:

- Choose an infusion area in the lower right or lower left of the abdomen below the navel
- Never infuse into areas where the skin is tender, bruised, red or hard. Avoid infusing into tattoos, scars or stretch marks. Rotate infusion sites from one infusion to the next
- Clean the skin at the infusion site using an alcohol wipe. Allow the skin to dry

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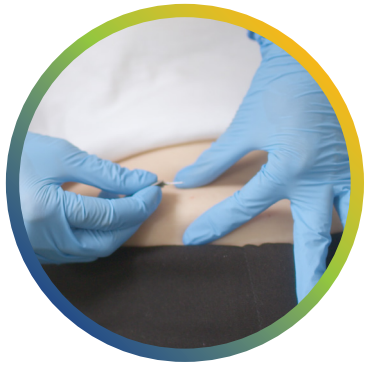

Insert the infusion set needle[1]:

- Using two fingers pinch the skin together around the infusion site. With a quick dart-like motion, insert the infusion set needle into the subcutaneous tissue

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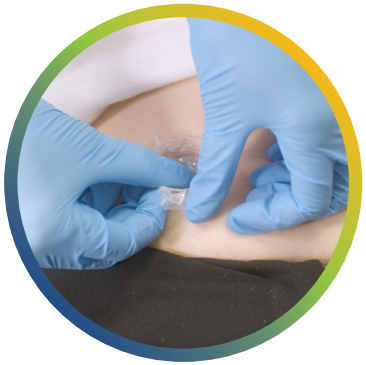

Secure the needle to the skin[1]:

- Put sterile gauze and tape or a transparent dressing over the infusion site to hold the needle in place

Start infusion[1]:

- Follow the manufacturer's instruction to turn on the infusion pump. Infuse RYSTIGGO at a constant flow rate up to 20 ml per hour
- Monitor patients during treatment with RYSTIGGO and for 15 minutes after the administration is complete for clinical signs and symptoms of hypersensitivity reactions

AFTER THE INFUSION

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End infusion[1]:

- Do not flush the infusion line as the volume of infusion has been adjusted taking into account losses in the line
- Remove needle from the infusion site
- Continue to monitor the patient for 15 minutes for signs and symptoms of hypersensitivity reactions

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Clean up[1]:

- If applicable, remove adapter from the infusion pump following the manufacturer's instructions
- Throw away empty and/or partial RYSTIGGO vials, along with used disposable supplies, according to local requirements.
  DO NOT REUSE CONTENTS IN PARTIAL VIAL(S)
- Clean and store the infusion pump, following the manufacturer's instructions

For further details about the technical requirements of infusion pumps and ancillaries, refer to the RYSTIGGO Subcutaneous Infusion Administration Handbook US-P-RZ-MG-2300293.

For more information contact your local UCBCares

Reference:

1. RYSTIGGO [Prescribing Information]. Smyrna, GA: UCB, Inc.

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