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

Product Information

Product Specifications[1]

RYSTIGGO (rozanolixizumab-noli) injection is a sterile, preservative-free, clear to slightly opalescent, colorless to pale brownish yellow solution supplied as a:

Formulation	Carton dimensions	Strength	Package size*	NDC
Injection for subcutaneous infusion	2.55 in (h) x 3.43 in (w) x 1.6125 in (d)	280 mg/2 mL (140 mg/mL)	2-mL, single-dose glass vial in a carton	50474-980-79 50474-0980-79†
		420 mg/3 mL (140 mg/mL)	3-mL, single-dose glass vial in a carton	50474-981-83 50474-0981-83†
		560 mg/4 mL (140 mg/mL)	4-mL, single-dose glass vial in a carton	50474-982-84 50474-0982-84†
		840 mg/6 mL (140 mg/mL)	6-mL, single-dose glass vial in a carton	50474-983-86 50474-0983-86†

*Each vial is intended for single-dose use only.
†For certain purposes, including the proper billing of drug products, an 11-digit NDC may be required.

Storage and Handling[1]

- **Store vials refrigerated** at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light until time of use. Do not freeze. Do not shake
- If needed, vials **may be stored at room temperature** up to 77°F (25°C) for **a single period of up to 30 days** in the original carton to protect the vial from light
- Once a vial has been stored at room temperature, **it should not be returned to the refrigerator**
- The discard date is 30 days after removal of the vial from the refrigerator. **Write the discard date in the space provided on the carton**
- **Discard** the vial if not used **within 30 days** or if the **expiration date has passed**, whichever occurs first

Recommended Equipment[1]

Supplies needed for administering RYSTIGGO (rozanolixizumab-noli):

Infusion pump with occlusion alarm limits at maximum setting

≤61-cm administration tubing

Infusion set with a ≥26-gauge or larger needle

Device shown was used in RYSTIGGO clinical trials and is one of several that can be used for administration.

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

RYSTIGGO is associated with important warnings and precautions, including increase risk of infection, drug-induced aseptic meningitis, and hypersensitivity reactions. The most common adverse reactions (≥10%) in patients with gMG are headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea.

NDC=National Drug Code.

Please refer to the next page for additional Important Safety Information.
Please refer to the full Prescribing Information provided by the UCB representative and visit RYSTIGGOhcp.com.

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Product Information (cont'd)

Dosage and Administration[1]

The recommended dosage of RYSTIGGO is based on body weight.

Body weight of patient	Dose	Dosage volume
<50 kg	420 mg	3 mL
≥50 kg to <100 kg	560 mg	4 mL
≥100 kg	840 mg	6 mL

- RYSTIGGO is administered as a subcutaneous infusion once weekly for 6 weeks
  - If a scheduled dose is missed, RYSTIGGO may be administered up to 4 days after the scheduled time point
  - Thereafter, resume the original dosing schedule until the treatment cycle is completed

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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

Immunization

Immunization with vaccines during RYSTIGGO treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because RYSTIGGO causes a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with RYSTIGGO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with RYSTIGGO.

Aseptic Meningitis: Serious adverse reactions of aseptic meningitis (also called drug-induced aseptic meningitis) have been reported in patients treated with RYSTIGGO. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

Hypersensitivity Reactions: Hypersensitivity reactions, including angioedema and rash, were observed in patients treated with RYSTIGGO. Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor patients during treatment with RYSTIGGO and for 15 minutes after for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs, institute appropriate measures if needed.

ADVERSE REACTIONS

In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of RYSTIGGO-treated patients) were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. Serious infections were reported in 4% of patients treated with RYSTIGGO. Three fatal cases of pneumonia were identified, caused by COVID-19 infection in two patients and an unknown pathogen in one patient. Six cases of infections led to discontinuation of RYSTIGGO.

Please refer to the full Prescribing Information provided by the UCB representative and visit RYSTIGGOhcp.com.

For more information about RYSTIGGO, visit RYSTIGGOhcp.com.

For additional information, contact UCBCares® at 1-844-599-CARE (2273).

Reference: 1. RYSTIGGO [prescribing information]. Smyrna, GA: UCB, Inc.

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