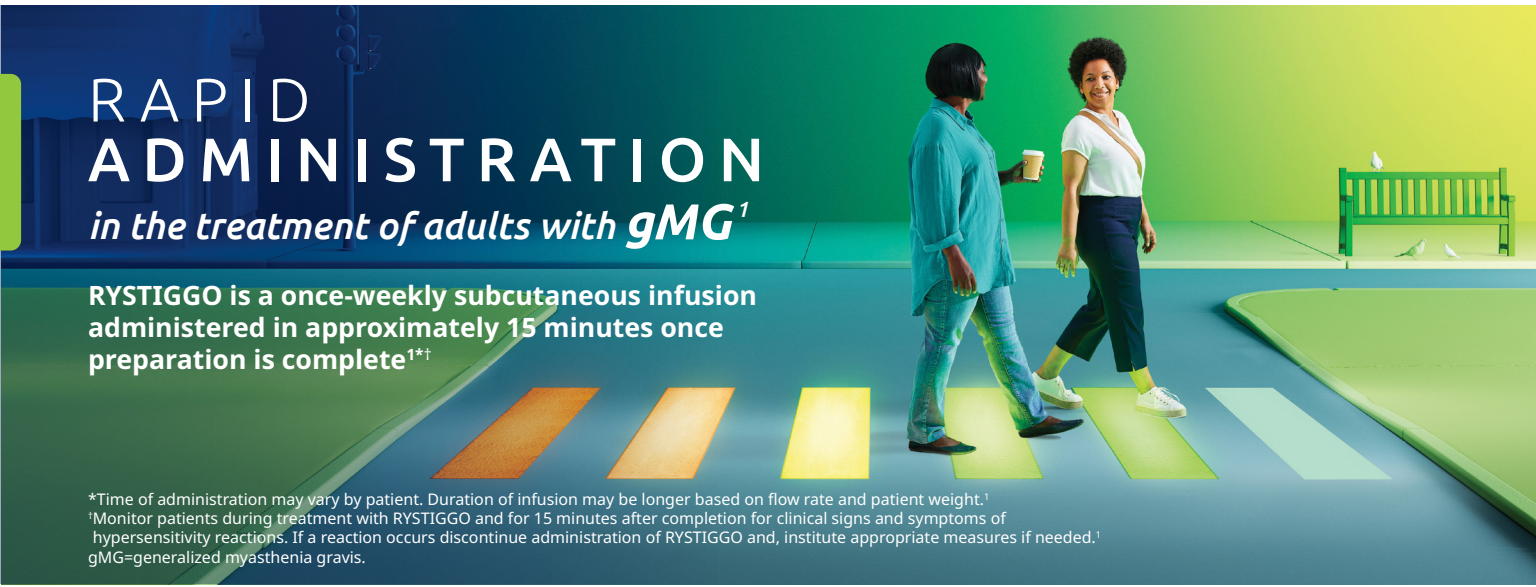
RYSTIGGO®
(rozanolixizumab-noli)
Injection For Subcutaneous Use
140 mg/mL

DOSING GUIDE



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 increased 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.

Please see the full Important Safety Information inside this guide and the full Prescribing Information.

Once-weekly subcutaneous infusion administered in approximately 15 minutes once preparation is complete[1]

Administration:

- Time of administration may vary by patient. Duration of infusion may be longer based on flow rate and patient weight[1]
- RYSTIGGO is intended to be infused in the lower right or lower left part of the abdomen below the navel[1]
- Do not infuse where the skin is tender, bruised, red, or hard. Avoid infusing into tattoos, scars, or stretch marks[1]
- Rotate infusion sites for subsequent administrations[1]

Observation:

- Monitor patients during treatment with RYSTIGGO and for 15 minutes after completion for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs, institute appropriate measures if needed[1]
- In clinical trials, hypersensitivity reactions occurred within 1 day to 2 weeks of administration. One patient discontinued RYSTIGGO due to a hypersensitivity reaction. Local reactions at the administration site occurred within 1 to 3 days after the most recent RYSTIGGO infusion[1]

Please see the full Prescribing Information for RYSTIGGO administration instructions.

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.

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Administered once-weekly by a healthcare professional in 6-week cycles, with every cycle followed by an individualized break in treatment[1]*

In RYSTIGGO clinical studies[1]:

- **8 weeks** of observation followed the 6-week treatment period
  - The safety of initiating subsequent cycles sooner than 9 weeks (63 days) from the start of the previous treatment cycle has not been established
- **4 treatment cycles** were initiated per year, on average (range: 1-7 cycles)

*RYSTIGGO is intended for subcutaneous administration using an infusion pump at a constant flow rate of up to 20 mL/hr.[1]

IMPORTANT SAFETY INFORMATION

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.

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Dosage is based on body weight[1]

Body weight of patient	Dose	Vial strength	Dosage volume
<50 kg	420 mg	420 mg/3 mL (140 mg/mL)	3 mL
50 to <100 kg	560 mg	560 mg/4 mL (140 mg/mL)	4 mL
≥100 kg	840 mg	840 mg/6 mL (140 mg/mL)	6 mL

- RYSTIGGO is administered as a subcutaneous infusion once weekly for 6 weeks[1]
  - If a scheduled infusion is missed, RYSTIGGO may be administered up to 4 days after the scheduled time point[1]
  - Thereafter, resume the original dosing schedule until the treatment cycle is completed[1]

Consider the need for future cycles when prescribing RYSTIGGO.[1]

Infusions can be administered in different settings (to fit individual patients' needs)

- Physician office infusion suite
- Independent infusion center
- Hospital outpatient department
- At home, when administered by a trained nurse*

RYSTIGGO is for subcutaneous administration only using an infusion pump at a constant flow rate of up to 20 mL/hr[1]

- It is recommended to use pumps where the administered volume can be pre-set, as each vial contains excess volume for priming of the infusion line[1]
- Refer to the infusion pump manufacturer's instructions for full preparation and administration information[1]

*Eligibility is determined by a patient's insurance. Not all patients are eligible.

IMPORTANT SAFETY INFORMATION

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.

Please see the full Important Safety Information inside this guide and the full Prescribing Information.

Administration considerations[1]

Infections

- 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

- Because RYSTIGGO causes a reduction in immunoglobulin G (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

Hypersensitivity reactions

- Angioedema and rash have occurred in patients treated with RYSTIGGO. Monitor patients during treatment with RYSTIGGO and for 15 minutes after the administration is complete for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention

Effect of RYSTIGGO on other drugs

- Concomitant use of RYSTIGGO with medications that bind to the human neonatal Fc receptor (FcRn) (eg, immunoglobulin products, monoclonal antibodies, or antibody derivatives containing the human Fc domain of the IgG subclass) may lower systemic exposures and reduce effectiveness of such medications

For more information about RYSTIGGO dosing and administration, scan the QR code or visit RystiggoHCP.com/dosing.

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WARNINGS AND PRECAUTIONS

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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.

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RAPID **ADMINISTRATION**

in the treatment of adults with ***gMG***[1]

- Convenient, subcutaneous infusion[1-3*]
- Administered in approximately 15 minutes[1†‡]
- Individualized cyclic treatment[1§‖]

Go to **RystiggoHCP.com** to learn more about how RYSTIGGO may help your patients with anti-AChR Ab+ or anti-MuSK Ab+ gMG.

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*RYSTIGGO is intended for subcutaneous administration using an infusion pump at a constant flow rate of up to 20 mL/hr.[1]

†Time of administration may vary by patient. Duration of infusion may be longer based on flow rate and patient weight.[1]

‡Monitor patients during treatment with RYSTIGGO and for 15 minutes after for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs discontinue administration of RYSTIGGO and, institute appropriate measures if needed.[1]

§If a scheduled infusion 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.[1]

‖The average number of cycles initiated per year was 4 (range: 1-7 cycles). The safety of initiating subsequent cycles sooner than 9 weeks (63 days) from the start of the previous treatment cycle has not been established.[1]

Ab+=antibody positive; AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; MuSK=muscle-specific tyrosine kinase.

References: 1. RYSTIGGO [Prescribing Information]. Smyrna, GA: UCB, Inc. **2.** Jonaitis L, Marković S, Farkas K, et al. Intravenous versus subcutaneous delivery of biotherapeutics in IBD: an expert's and patient's perspective. *BMC Proc.* 2021;15(suppl 17):25. doi:10.1186/s12919-021-00230-7 **3.** Santus P, Ferrando M, Baiardini I, et al. Patients beliefs on intravenous and subcutaneous routes of administration of biologics for severe asthma treatment: a cross-sectional observational survey study. *World Allergy Organ J.* 2019;12(4):100030. doi:10.1016/j.waojou.2019.100030