

RYSTIGGO[®]
(rozanolixizumab-noli)
Injection For Subcutaneous Use
280 mg/2 mL vial

DOSING GUIDE



RAPID ADMINISTRATION

in the treatment of adults with gMG¹

RYSTIGGO is a once-weekly subcutaneous infusion administered in approximately 15 minutes once preparation is complete^{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, institute appropriate measures if needed.¹
gMG=generalized myasthenia gravis.



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 ($\geq 10\%$) 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](#).

RYSTIGGO[®] (rozanolixizumab-noli) is a once-weekly subcutaneous infusion administered in approximately 15 minutes once preparation is complete¹



Administration:

- Time of administration may vary by patient. Duration of infusion may be longer based on flow rate and patient weight¹
- RYSTIGGO is intended to be infused in the lower right or lower left part of the abdomen, below the navel. Do not infuse where the skin is tender, bruised, red, or hard. Avoid infusing into tattoos, scars, or stretch marks¹
- Rotate infusion sites for subsequent administrations¹
- Infuse RYSTIGGO within 4 hours of puncturing the vial. RYSTIGGO should be administered immediately after priming the infusion set¹

Observation:

- Hypersensitivity reactions, including angioedema and rash, have occurred. 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 needed¹

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.

Please see the full Important Safety Information [inside this guide](#) and the full [Prescribing Information](#).



RYSTIGGO[®] (rozanolixizumab-noli) is administered by a healthcare professional in a 6-week treatment cycle^{1*}



In RYSTIGGO clinical studies¹:

- **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.

Please see the full Important Safety Information [inside this guide](#) and the full [Prescribing Information](#).



RYSTIGGO[®] dosage is based on body weight¹

RYSTIGGO is supplied in 280 mg/2 mL (140 mg/mL) single-dose vials¹

Body weight of patient	Dose	Dosage volume	Vials per dosage	Vials per cycle
<50 kg	420 mg	3 mL	2 vials	12 vials
50 to <100 kg	560 mg	4 mL	2 vials	12 vials
≥100 kg	840 mg	6 mL	3 vials	18 vials

- If a scheduled infusion is missed, RYSTIGGO may be administered up to 4 days after the scheduled time point¹
 - Thereafter, resume the original dosing schedule until the treatment cycle is completed¹



Consider the need for future cycles when prescribing RYSTIGGO.¹

IMPORTANT SAFETY INFORMATION

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.

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RYSTIGGO infusions can be administered in different settings



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/hr¹

- 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 line¹
- Refer to the infusion pump manufacturer's instructions for full preparation and administration information¹

*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.

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Administration considerations with RYSTIGGO[®] (rozanolixizumab-noli)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.

Please see the full Important Safety Information [inside this guide](#) and the full [Prescribing Information](#).



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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.

Please see the full [Prescribing Information](#).

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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Convenient, subcutaneous infusion^{1-3*}



Administered in approximately 15 minutes^{1††}



Individualized cyclic treatment^{1§||}



Go to [RystiggoHCP.com](https://www.rystiggohcp.com) to learn more about how RYSTIGGO may help your patients with anti-AChR antibody positive or anti-MuSK antibody positive gMG.

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‡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.¹

§If a scheduled infusion is missed, RYSTIGGO may be administered up to 4 days after the scheduled time. 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

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.2019.10003



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