

Injection For Subcutaneous Use 140 mg/mL

REACH HIGHER with RYSTIGGO*

For adults with **GENERALIZED MYASTHENIA GRAVIS (gMG)**

CAREGIVER'S GUIDE

Use this guide for advice on supporting your loved one with gMG.

*Based on MG-ADL and QMG results at Day 43 vs placebo in the MycarinG clinical trial. Results may vary. No head-to-head trials were conducted.

MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG=Quantitative Myasthenia Gravis.

INDICATION

RYSTIGGO is a prescription medicine used to treat adults with a disease called generalized myasthenia gravis (gMG) who are acetylcholine receptor (anti-AChR) antibody positive or muscle-specific tyrosine kinase (anti-MuSK) antibody positive.

IMPORTANT SAFETY INFORMATION

RYSTIGGO may increase the risk of infection and could cause aseptic meningitis. Tell your healthcare provider right away if you have signs or symptoms of an infection or meningitis during treatment with RYSTIGGO. Swelling and rash have also occurred. Tell your healthcare provider immediately about any undesirable reactions you experience after administration. The most common side effects of RYSTIGGO include headache, infections, diarrhea, fever, hypersensitivity reactions, and nausea.



Providing support for people living with gMG

As a caregiver for your loved one living with generalized myasthenia gravis (gMG), your day-to-day routine can change, as well as your role

On any given day, you could be:

- Providing help with daily tasks such as bathing, mobility, or eating
- Giving emotional support on tougher days
- Staying on top of infusion schedules and lending a hand on infusion days
- Helping manage any side effects of treatment
- Arranging emergency support for debilitating gMG symptoms, such as breathing impairment

About gMG and your role as a caregiver

Generalized myasthenia gravis, or gMG, is a severe type of myasthenia gravis (MG) that can weaken muscles throughout the body. gMG is unpredictable, with debilitating and fluctuating symptoms.

Everyone experiences gMG differently, and some people may need more support than others. On a given day, you may need to help your loved one with medication management, emotional support, or both.

Due to gMG fluctuations and flare-ups, your loved one may experience:

- Severe and unpredictable muscle weakness: This may cause struggles with activities of daily living. You may need to watch whether your loved one is experiencing difficulty rising from a chair, swallowing, talking, or brushing their hair or teeth
- **Breathing difficulties:** In some cases, gMG may affect the muscles involved in breathing. Your loved one may even need help with monitoring and assistance in the event of an emergency, such as a myasthenic crisis

Providing support for people living with gMG

During myasthenic crises and/or any medical emergencies:

- Call for immediate medical support
- Follow any emergency protocol that your loved one's doctor may provide



Myasthenic crisis versus flare-up

A **myasthenic crisis** is a life-threatening weakness in the muscles that control breathing, resulting in respiratory failure. This is a medical emergency and requires immediate treatment.

An **MG flare-up** (also called exacerbation) is a worsening of MG symptoms and/or an increase in symptom severity that may impact muscles throughout the body. It may be uncomfortable but is not usually an emergency. People experiencing flare-ups do not typically require breathing assistance.

Taking care of your loved one starts with taking care of you

Supporting yourself is important while providing care for your loved one. Here are a few things you can try:

- MG support groups: Reach out to support groups, which offer MG education and caregiver support
- Physical care: Get enough sleep, eat healthy, and exercise
- Caring for your mental health: Take a break during the day to do things you enjoy, speak to a therapist, or try to make time for socializing with friends or other family members



Where can I find support locally?

The UCB advocacy team can help you reach out to patient support and advocacy organizations in your area. Email **MGAdvocacy@ucb.com**

On the following pages, learn more about a treatment option that may help your loved one with gMG.

RYSTIGGO clinical trial results

RYSTIGGO was studied in a large clinical trial (200 participants) specifically for people with gMG

Understanding how the clinical trial was designed may help you better understand its results.

The RYSTIGGO clinical trial included adults with gMG who were anti-AChR or anti-MuSK antibody positive.

200 people were divided into 3 groups:

Those taking 7 mg/kg of RYSTIGGO (66 participants)

Those taking 10 mg/kg of RYSTIGGO (67 participants)

Those taking placebo (67 participants)

People in the study:

Received 1 dose each week for **6 weeks** in addition to their current gMG treatment

Followed the 6-week treatment period with an observation period of **up to 8 weeks**

DID YOU KNOW?

UP TO

95 % of people with gMG

have anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibodies

gMG GLOSSARY

Acetylcholine receptor antibody: A protein found in the blood of many people with gMG. The AChR antibody affects signals that are sent from nerves to muscles.

Antibody: A protein that is part of the immune system. When acting normally, antibodies protect you by attacking foreign substances that enter the body such as bacteria and viruses.

Muscle-specific tyrosine kinase (MusK): A type of antibody that may disrupt communication between nerve and muscle. A small number of people with gMG are anti-Musk antibody positive.



RYSTIGGO clinical trial results



Significant improvement in activities of daily living

Participants receiving RYSTIGGO **experienced significant improvement in MG-ADL** by the end of the 6-week treatment period.

As determined by improvement in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score from baseline on Day 43 of the study; -3.4 points in the RYSTIGGO-treated group (133 people) vs -0.8 in the placebo group (67 people).

Individual results may vary, and not all people taking RYSTIGGO will experience improvements.



Rapid improvement by the end of Week 6

RYSTIGGO was shown to significantly improve MG-ADL scores by the end of the 6-week treatment period. Improvements were seen in some participants as early as 1 week after their first dose.

35% (23 out of 66 people) of the 7 mg/kg group and 38% (25 out of 66) of the 10 mg/kg group responded to treatment by Day 8, compared with 24% (16 out of 67) of the placebo group.

gMG GLOSSARY

Myasthenia Gravis Activities of Daily Living (MG-ADL) scale: A questionnaire that measures how much gMG symptoms affect 8 functional activities of daily living: breathing, talking, chewing, swallowing, actions such as brushing teeth and rising from a chair, and double vision and eyelid droop. The total score ranges from 0 to 24; a lower MG-ADL score indicates less impairment.



UCB is grateful to all those living with gMG, and the doctors and nurses, who participated in this trial.



IMPORTANT SAFETY INFORMATION

The most common side effects of RYSTIGGO include headache, infections, diarrhea, fever, hypersensitivity reactions, and nausea.

RYSTIGGO® clinical trial results



The first treatment of its kind for anti-MuSK antibody-positive gMG

All 12 participants with anti-MuSK antibody-positive gMG who received RYSTIGGO (rozanolixizumab-noli) improved their MG-ADL scores.

Caution must be used when interpreting as conclusions cannot be drawn. Results may vary.

The study did not compare improvements in anti-MuSK antibody-positive participants to those who were anti-AChR antibody positive and received RYSTIGGO (120 participants).



Over 25% of participants receiving RYSTIGGO in the clinical trial achieved MSE

Minimal Symptom Expression (MSE) is sometimes used as a treatment goal for gMG, and is defined as a total MG-ADL score of 0 or 1. People who reach MSE experience minimal symptoms as assessed by the MG-ADL scale.

MSE was an exploratory outcome in the clinical trial, not a primary or secondary outcome. Caution must be used when interpreting as conclusions cannot be drawn. Results may vary.

26% (17 out of 66 people) in the 7 mg/kg group and 28% (19 out of 67 people) in the 10 mg/kg group, compared with 3% (2 out of 67 people) in the placebo group.

Ask your loved one's doctor if RYSTIGGO could be right for them.

IMPORTANT SAFETY INFORMATION

RYSTIGGO may increase the risk of infection. In clinical studies, the most common infections were upper respiratory tract infections, COVID-19, urinary tract infections, and herpes simplex infections. Your healthcare provider should check you for infections before starting and during treatment with RYSTIGGO. Tell your healthcare provider if you have any history of infections. Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with RYSTIGGO.

The safety of RYSTIGGO in the clinical trial

Side effects in the clinical trial

This chart includes side effects experienced by at least 5% of people treated with RYSTIGGO during the clinical trial. They were also felt more often in the RYSTIGGO group than in the placebo group.

Side effect	RYSTIGGO (133 people)	Placebo (67 people)
Headache	44%	19%
Any infection	23%	19%
Upper respiratory tract infection	8%	6%
Diarrhea	20%	13%
Fever	17%	2%
Hypersensitivity reactions	11%	5%
Nausea	10%	8%
Administration site reactions	8%	3%
Abdominal pain	8%	6%
Joint pain/stiffness	7%	3%



Encourage your loved one to ask their doctor about RYSTIGGO and their treatment goals.



Your loved one will receive one dose per week for 6 consecutive weeks

This 6-week period is called a treatment cycle. Every cycle is followed by a break. The length of the break is unique to to each person receiving RYSTIGGO treatment.



^{*}In a long-term study, the shortest length of time between the start of treatment cycles was 9 weeks (63 days). The safety of starting later cycles sooner than 63 days from the start of the previous cycle has not been established.

Because everyone responds to RYSTIGGO differently, the length of the treatment break will be specific to your loved one's individual treatment needs, and their doctor may adjust it following any future RYSTIGGO treatments.

Your loved one should always take RYSTIGGO as prescribed. Even if your loved one begins to feel better, they should not skip an infusion or discontinue treatment without speaking to their doctor.

IMPORTANT SAFETY INFORMATION

RYSTIGGO could cause aseptic meningitis. Tell your healthcare provider right away if you develop any signs or symptoms of meningitis during treatment with RYSTIGGO.





During treatment break:

It's important to help monitor your loved one's progress. After a treatment cycle, help them work with their doctor to determine if or when another cycle is needed.



Track

RYSTIGGO® (rozanolixizumab-noli) works only during a treatment cycle, so it's important to keep an eye out for any symptoms that may return during the treatment break.



Discuss

Stay in touch with the doctor during both treatment and break, and be sure to mention any side effects or symptoms you observe.



Plan

Your loved one's doctor will use the information you or your loved one provide, along with medical evaluation, to determine if additional cycles of RYSTIGGO are needed, and when to start them.

IMPORTANT SAFETY INFORMATION



RYSTIGGO can cause swelling and rash. Your healthcare provider should monitor you during and after treatment and discontinue RYSTIGGO if needed. Tell your healthcare provider immediately about any undesirable reactions you experience after administration.

Once prepared by a healthcare professional, RYSTIGGO is given in about 15 minutes*:



- As a subcutaneous infusion, where a needle is inserted under the surface of the skin.[†]
- At an infusion center, doctor's office, or outpatient hospital clinic. At-home infusions with a nurse's assistance may also be available.[‡]
- Followed by an additional 15-minute period for routine monitoring, once the infusion is complete.

Your loved one's doctor can provide more information about subcutaneous infusions and what to expect on infusion days.

gMG GLOSSARY

Infusion: A method of delivering medicine to the body. Subcutaneous (under the skin) infusions are typically administered by a healthcare professional using an infusion pump to regulate the rate at which medicine is delivered.

IMPORTANT SAFETY INFORMATION

The use of vaccines during RYSTIGGO treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live attenuated vaccines is not recommended during treatment with RYSTIGGO. Completion of age-appropriate vaccines according to vaccination guidelines before starting a new treatment cycle with RYSTIGGO is recommended.



^{*}There are 3 recommended doses of RYSTIGGO, based on body weight. Preparation and infusion time may vary by patient, dosage, and/or infusion provider or provider location.

[†]In the lower abdomen below the belly button. Do not receive RYSTIGGO in areas where the skin is tender, bruised, red, or hard, or contains tattoos, scars, or stretch marks.

^{*}At-home infusions, with nurse assistance, are available based on insurance eligibility determination.



Before your loved one receives RYSTIGGO® (rozanolixizumab-noli), they should tell their healthcare provider about all of their medical conditions, including if they:

- Have a history of infection or think they have an active infection.
- Have received or are scheduled to receive a vaccine (immunization).
- Are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed.
- Are taking any medicines, including prescription and over-thecounter medicines, vitamins, and herbal supplements.



Helpful resources & support

RYSTIGGO.com is your source for treatment education, connection, and more



Find educational resources

Download the Doctor Discussion Guide, MG-ADL Tool, and other helpful resources.



Locate a doctor near you

Use the online doctor locator to help your loved one find a doctor with gMG expertise in your area.

Results shown may not be inclusive of all providers in your area. UCB, Inc. does not guarantee the accuracy or completeness of any information provided herein. Contact providers directly regarding any treatment, insurance coverage, facility, or other site-specific inquiries.



Find an infusion center near you

If your loved one is looking for a nearby infusion center, RYSTIGGO.com can help them get started.

The Find an Infusion Center tool is for informational purposes only. Please consult your loved one's healthcare provider to discuss the best place to receive infusions. Inclusion in this list does not guarantee that treatment will be covered by the healthcare insurance plan. Please contact the healthcare insurance provider before starting treatment at an infusion center.



Connect with the gMG community

Reach out to gMG advocacy groups and learn more about local organizations that may help.



Share your RYSTIGGO story

Learn how your story can help inspire other gMG caregivers by visiting RYSTIGGO.com or calling 833-279-1996.



Discover personalized support, made for people living with gMG



ONWARD™ was created with the help of rare disease patients and healthcare providers.

Once prescribed RYSTIGGO® (rozanolixizumab-noli), your loved one can begin a support experience that is there for them every step of the way.

Personalized support offerings include:



A medically trained ONWARD Care Coordinator personally assigned to your loved one.*



Tools and resources to help the one you care for get started on treatment and continue prescribed treatment.



Help with reviewing insurance coverage and potential financial assistance options, even if your loved one is uninsured.



Guidance with symptom tracking and ongoing treatment support.

ONWARD is provided as a service of UCB and is intended to support the appropriate use of UCB medicines. ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.

^{*}ONWARD Care Coordinators do not provide medical advice and will refer you to your healthcare professional for any questions related to your treatment plan.

Important Safety Information

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT RYSTIGGO (rozanolixizumab-noli)?

RYSTIGGO may cause serious side effects, including:

- **Infection:** RYSTIGGO may increase the risk of infection. In clinical studies, the most common infections were upper respiratory tract infections, COVID-19, urinary tract infections, and herpes simplex infections. Your healthcare provider should check you for infections before starting and during treatment with RYSTIGGO. Tell your healthcare provider if you have any history of infections. Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with RYSTIGGO. Some of the signs and symptoms may include fever, chills, frequent and/or painful urination, cough, runny nose, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.
- **Aseptic Meningitis:** RYSTIGGO could cause aseptic meningitis. Tell your healthcare provider right away if you develop any signs or symptoms of meningitis during treatment with RYSTIGGO such as severe headache, neck stiffness, drowsiness, fever, sensitivity to light, painful eye movements, nausea, and vomiting.
- **Hypersensitivity Reactions:** RYSTIGGO can cause swelling and rash. Your healthcare provider should monitor you during and after treatment and discontinue RYSTIGGO if needed. Tell your healthcare provider immediately about any undesirable reactions you experience after administration.

Before taking RYSTIGGO, tell your healthcare provider about all of your medical conditions, including if you:

- Have a history of infection or think you have an active infection
- Have received or are scheduled to receive a vaccine (immunization). The use of vaccines during RYSTIGGO treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with RYSTIGGO. Completion of age-appropriate vaccines according to vaccination guidelines before starting a new treatment cycle with RYSTIGGO is recommended.
- Are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



Important Safety Information (continued)

WHAT ARE THE POSSIBLE SIDE EFFECTS OF RYSTIGGO?

RYSTIGGO may cause serious side effects, including:

See "What is the most important information I should know about RYSTIGGO?"

The most common side effects of RYSTIGGO include:

- headache
- infections
- diarrhea
- fever
- hypersensitivity reactions
- nausea

These are not all the possible side effects of RYSTIGGO. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away. Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to UCB, Inc. by calling 1-844-599-CARE [2273].

Please see the full <u>Prescribing Information</u> at RYSTIGGO.com and talk to your healthcare provider about your condition or your treatment. For more information, go to <u>RYSTIGGO.com</u> or call 1-844-599 2273.

WHAT IS RYSTIGGO?

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RYSTIGGO®
(rozanolixizumab-noli)
Injection For Subcutaneous Use

REACH HIGHER with RYSTIGGO*

Ask your loved one's doctor about a targeted treatment for adults with **GENERALIZED**MYASTHENIA GRAVIS (gMG)



MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG=Quantitative Myasthenia Gravis.



Sign up for emails by scanning the QR code or visiting RYSTIGGO.com

INDICATION

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