

**RYSTIGGO**<sup>®</sup>  
(rozanolixizumab-noli)  
Injection For Subcutaneous Use  
280 mg/2 mL vial



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

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## **A CAREGIVER'S GUIDE**

Use this guide for advice on supporting your loved one with gMG, for help with having informed discussions with their doctor, and to learn more about RYSTIGGO.

### **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.


Please see full Important Safety Information on pages 9-10 and the accompanying full Prescribing Information.

# Flexibility is important when caring for your loved one

## As a caregiver for your loved one living with 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 providing a helping hand on infusion days
- Helping manage any side effects of treatment
- Arranging emergency support for debilitating gMG symptoms, such as breathing impairment



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

# Providing support for people living with gMG

## Your unique role as a caregiver

gMG is an unpredictable disease with debilitating and fluctuating symptoms. Everyone experiences gMG differently, and some may need more support than others. On a given day, you may need to support them 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

### 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. This is a medical emergency and requires immediate treatment. A **flare-up** (also called an exacerbation) is a worsening of MG symptoms and/or an increase in symptom severity. It may be uncomfortable but is not usually an emergency.

### 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:** Do things you enjoy for a break during the day, speak to a therapist, or try to make time for socializing with friends or other family members



#### Where can I find support locally?

You can be connected to patient support and advocacy organizations in your area by emailing the UCB advocacy team at [MGAdvocacy@ucb.com](mailto:MGAdvocacy@ucb.com).

### 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.

UP TO **95%**

of people with gMG are anti-AChR or anti-MuSK antibody positive

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 people)
- Those taking 10 mg/kg of RYSTIGGO (67 people)
- Those taking placebo (67 people)

People in the study:

- Received 1 dose each week for **6 weeks**, in addition to their current gMG treatment
- Underwent a 6-week treatment period followed by an observation period of **up to 8 weeks**

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

Please see full Important Safety Information on pages 9-10 and the accompanying full Prescribing Information.

# Results of the RYSTIGGO clinical trial



## Significant improvement in activities of daily living

RYSTIGGO significantly improved activities of daily living such as breathing, talking, swallowing, and being able to rise from a chair.\*

\*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.



## Up to 72% of people responded to treatment

Among clinical trial participants receiving RYSTIGGO, a majority experienced improvements in symptoms.† Caution must be used when interpreting as conclusions cannot be drawn. Results may vary.

†72% (46 out of 64 people) in the 7 mg/kg group and 69% (43 out of 62) in the 10 mg/kg group, compared to 31% (20 out of 64) in the placebo group, as determined by improvement in MG-ADL score from baseline on Day 43 of the study. Response was defined as at least a 2-point improvement in MG-ADL score from baseline by Day 43.



## Rapid improvement by the end of Week 6

RYSTIGGO was shown to significantly improve activities of daily living by the end of the 6-week treatment period. Improvements were seen in some participants as early as 1 week after the 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, compared to 24% (16 out of 67) of the placebo group, as determined by improvement in MG-ADL score.



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

All 12 participants with anti-MuSK antibody-positive gMG who received RYSTIGGO showed improvement in activities of daily living.‡ Caution must be used when interpreting as conclusions cannot be drawn. Results may vary.

‡As determined by improvement in their MG-ADL score. 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).

These results were measured using the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale. Study participants scored themselves on 8 functional activities commonly affected by gMG. A total MG-ADL score ranges from 0-24, with higher scores indicating more impairment.

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

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### IMPORTANT SAFETY INFORMATION

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

### IMPORTANT SAFETY INFORMATION

RYSTIGGO may increase the risk of infection. In a clinical study, the most common infections were respiratory tract infections and herpes simplex infections. Your healthcare provider should check you for infections before starting treatment, during treatment, and after 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.

Please see full Important Safety Information on pages 9-10 and the accompanying full Prescribing Information.

# The safety of RYSTIGGO in the clinical trial

The following side effects were experienced by 5% or more people taking RYSTIGGO, and more often than in those on placebo.

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%

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**Could RYSTIGGO be a treatment option for your loved one?**

Encourage them to speak to their doctor to learn more.



# Important Safety Information and Indication

## 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.

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## 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.

Please see the accompanying full [Prescribing Information](#) and talk to your healthcare provider about your condition or your treatment. For more information, go to [www.RYSTIGGO.com](http://www.RYSTIGGO.com) or call 1-844-599-2273.

## WHAT IS RYSTIGGO?

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.

# Understanding the infusion process

## RYSTIGGO is given once weekly in 6-week cycles

The 6-week period of RYSTIGGO treatment is called a treatment cycle. Every cycle is followed by a break in RYSTIGGO treatment.

Most people may require repeated cycles of RYSTIGGO to manage gMG symptoms.



The frequency of your loved one's RYSTIGGO treatment cycles and the length of breaks will be based on individual treatment experience and medical evaluation. Their doctor can explain more about the importance of the treatments. RYSTIGGO works only during a treatment cycle.



**In the clinical studies, participants started an average of 4 treatment cycles per year, with a range of 1-7 cycles.**  
For participants who started 4 cycles, the median length of the time between the start of treatment cycles was 14 weeks (98 days).


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### 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 RYSTIGGO treatment


Everyone responds to treatment differently, so 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**  
You can help your loved one keep track of any gMG symptoms that may return during breaks from treatment.



**Discuss**  
If any symptoms or side effects occur during or in between treatment cycles, discuss them with your loved one's doctor.



**Plan**  
With information that you help gather during the treatment cycle, your loved one's doctor can determine when they will begin the next RYSTIGGO treatment cycle. The exact time will be based on medical evaluation.

### IMPORTANT SAFETY INFORMATION

Swelling and rash have also occurred. 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.

Please see full Important Safety Information on pages 9-10 and the accompanying full Prescribing Information.

## Understanding the infusion process (continued)

Once prepared by a healthcare professional, RYSTIGGO is given as a subcutaneous infusion in about 15 minutes\*

RYSTIGGO is different than other treatments for gMG like oral medications or intravenous (IV) infusions. RYSTIGGO is a **subcutaneous infusion, where a needle is inserted under the surface of the skin.**<sup>†</sup> IV infusions use a needle inserted into a vein.

**Most people will receive RYSTIGGO at an infusion center or the doctor's office.** Some may be able to receive treatment at home with nurse assistance.<sup>‡</sup>

Your loved one will be monitored while receiving RYSTIGGO, and for 15 minutes after the infusion is complete. Your loved one's doctor can provide more information about subcutaneous infusions and what to expect on infusion days.



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

<sup>†</sup>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.

<sup>‡</sup>Eligibility for at-home infusions will be assessed by your doctor and could be based on your insurance coverage.

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### IMPORTANT SAFETY INFORMATION

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

**Before your loved one receives RYSTIGGO, they should inform 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

Your loved one's healthcare provider should be informed of all the medicines taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



**Your loved one should always take RYSTIGGO as prescribed.**

They should not skip an infusion or discontinue treatment without speaking to their doctor.

### 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.

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## 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, your loved one can begin a support experience that is there for them every step of the way.



### ONWARD provides:



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



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



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



Guidance with symptom tracking and ongoing treatment support.

\*ONWARD Care Coordinators do not provide medical advice and will refer your loved one to their healthcare professional for any questions related to their treatment plan.



### Join the ONWARD support program

You can ask your loved one's doctor to sign them up, scan the QR code to download the enrollment form, or call **1-844-ONWARD-1** for more information.

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.

## Helpful resources & support

### Your source for treatment education, connection, and more

RYSTIGGO.com has resources that can help both people living with gMG and their caregivers learn more about gMG and RYSTIGGO treatment.



Our **Doctor Discussion Guide** can help you and your loved one prepare for medical appointments.



The **MG-ADL and You tool** explains the value of the MG-ADL assessment in more detail.



Links to **gMG community and advocacy groups** are there for those seeking additional support.

Visit [RYSTIGGO.com/resources](https://www.rystiggo.com/resources) to learn more.



If your loved one is new to RYSTIGGO and is looking for a nearby infusion center, our **Find an Infusion Center tool** may be able to help.

Visit [RYSTIGGO.com/infusion-finder](https://www.rystiggo.com/infusion-finder) to 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.



**Acetylcholine receptor (AChR) antibody:** A protein found in the blood of many people with MG or 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.

**Autoimmune disease:** Conditions where the immune system mistakenly attacks the body's healthy cells, tissues, and structures.

**Immune system:** A system that helps protect your body from infection and disease using specialized cells and organs.

**Infusion:** A method of delivering medicine to the body. Infusions may be intravenous (into a vein) or subcutaneous (under the skin) and are typically administered by a healthcare professional using an infusion pump to regulate the rate at which the medicine is delivered.

**Intravenous (IV):** Into a vein. Some infusion treatments are given as intravenous infusions.

**MG flare-up:** A worsening of MG symptoms and/or an increase in symptom severity that may impact muscles throughout the body. People experiencing flare-ups do not typically require breathing assistance.

**Muscle-specific tyrosine kinase (MuSK):** A type of antibody that may disrupt communication between nerve and muscle, leading to gMG symptoms. A small number of people with gMG are anti-MuSK antibody positive.

**Myasthenia Gravis Activities of Daily Living (MG-ADL) scale:** An 8-category questionnaire that measures how much gMG symptoms affect certain functional activities of daily living, including breathing, talking, chewing, swallowing, actions such as brushing teeth and rising from a chair, as well as double vision and eyelid droop. The score ranges from 0 to 24; a higher MG-ADL score means more severe MG symptoms.

**Myasthenic crisis:** A life-threatening complication of MG characterized by severe weakness in the muscles that control breathing, resulting in respiratory failure that requires intubation and mechanical ventilation.

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### Want to learn even more about RYSTIGGO?

You can sign up for emails by **scanning the QR code** on the left or by **visiting [RYSTIGGO.com](https://www.rystiggo.com)**. You will receive:

- Educational resources
- Tools designed to help you talk to their doctor about RYSTIGGO
- Treatment support
- Helpful information to connect you with the gMG community

### INDICATION

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**Please see full Important Safety Information on pages 9-10 and the accompanying full Prescribing Information.**



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