

ZILBRYSQ[®]
(zilucoplan) Injection

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

IMAGINE

where you can go with ZILBRYSQ

Discover the **first FDA-approved, self-administered treatment** for adults with gMG who are anti-acetylcholine receptor (AChR) antibody positive.



INDICATION

ZILBRYSQ is a prescription medicine used to treat adults with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. It is not known if ZILBRYSQ is safe and effective in children.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

ZILBRYSQ is a medicine that affects part of your immune system. ZILBRYSQ may lower the ability of your immune system to fight certain infections. ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections. You must complete meningococcal vaccines. **Do not use ZILBRYSQ if you** have a *Neisseria meningitidis* infection. ZILBRYSQ may also increase the risk of other types of serious infections. Pancreatitis and pancreatic cysts have happened in people who use ZILBRYSQ. The most common side effects of ZILBRYSQ include injection site reactions, upper respiratory tract infections, and diarrhea.

Please see full Important Safety Information on pages 16-19 and [Medication Guide](#).

What are MG and gMG?

What is MG?

Myasthenia gravis (MG) is a chronic autoimmune disease that can make daily tasks more difficult.

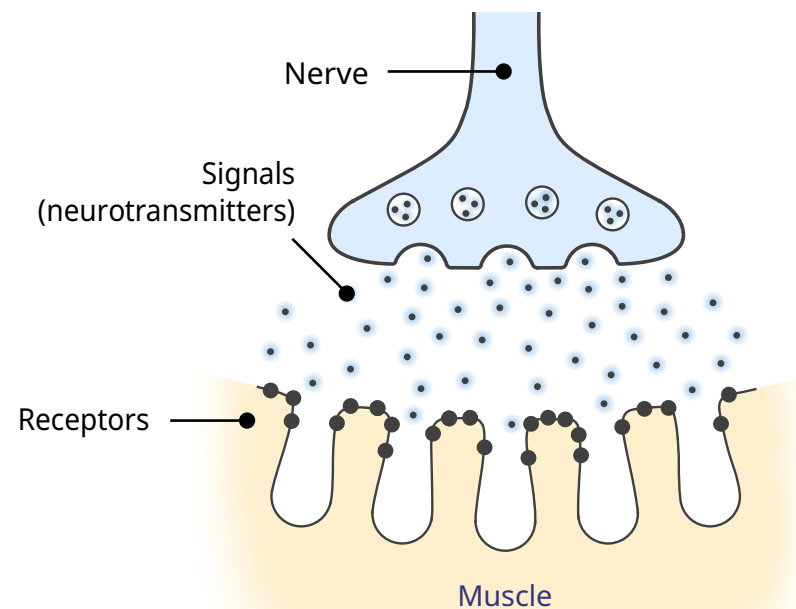
MG results from a problem in signaling between nerves and muscles. This problem happens in the neuromuscular junction, the place where nerves meet the muscles they control.

Generalized myasthenia gravis (gMG) is a more severe form of MG

gMG can affect nerves and muscles throughout the entire body. It can cause muscle weakness and fatigue that may feel overwhelming.

These symptoms can be debilitating and can make activities of daily living like climbing stairs, chewing, or brushing your teeth very challenging.

Neuromuscular junction with normal function



Signals are sent from nerves and received by muscles as part of normal muscle function and movement

What causes gMG and its symptoms?

gMG is caused by harmful antibodies in your immune system that get in the way of the signals between nerves and muscles at the neuromuscular junction.

Anti-AChR antibodies are the most common cause of gMG.

They trigger a part of your immune system called "complement," which activates proteins that attack your own muscle cells.

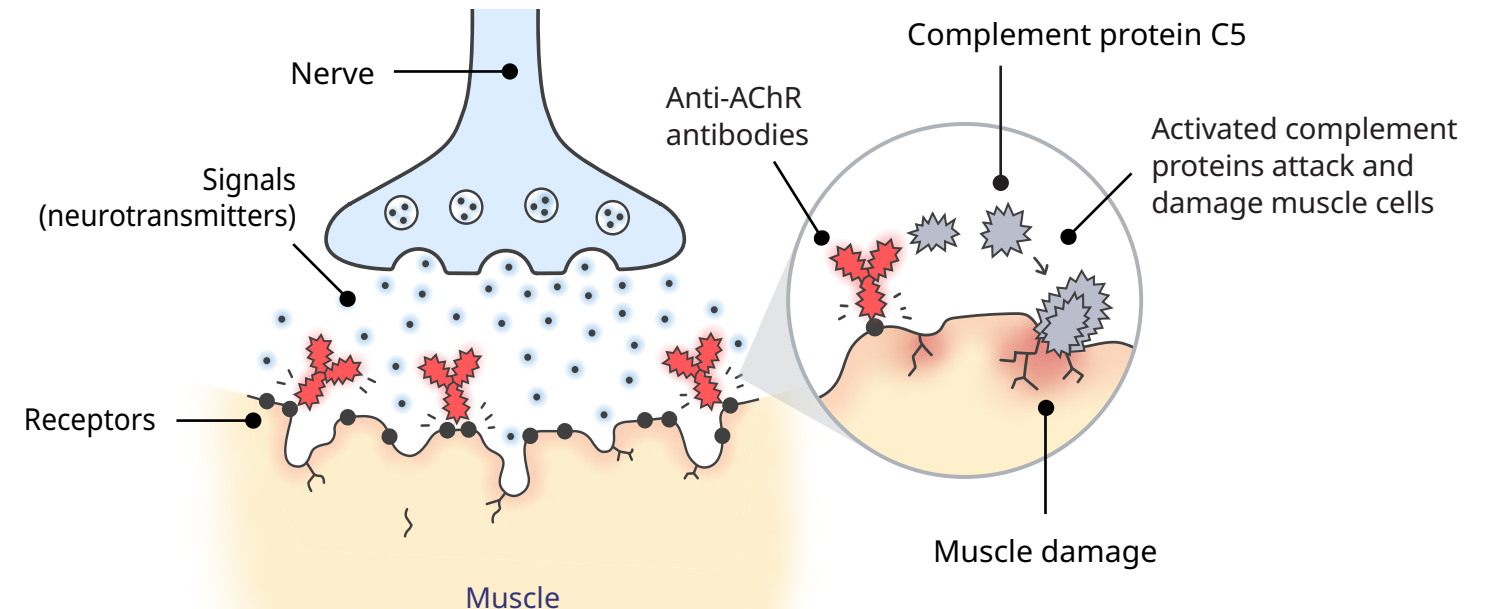
This limits your muscle's ability to receive signals from nerves, causing the weakness and fatigue you may feel.



Anti-AChR antibodies are found in about **80%-88% of people living with gMG.**

AChR=acetylcholine receptor.

Neuromuscular junction in gMG



Harmful antibodies disrupt these signals from the nerve and activate the complement system, resulting in damage to the muscle cells and the symptoms of gMG

About ZILBRYSQ® (zilucoplan)

ZILBRYSQ was studied in a large clinical trial (174 participants) specifically for adults with anti-AChR antibody-positive gMG

174 participants were randomly divided into 2 groups:

- Those taking 0.3 mg/kg of ZILBRYSQ (86 participants)
- Those taking placebo (88 participants)

Participants in the study:

- Took 1 dose each day for 12 weeks, in addition to their current gMG treatment

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



Significant improvements in the activities of daily living

ZILBRYSQ significantly improved activities of daily living such as breathing, talking, swallowing, and being able to rise from a chair.* Individual results may vary, and not all people taking ZILBRYSQ will experience improvements.

*As determined by improvement in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score from baseline on Week 12 of the study; -4.4 points in the ZILBRYSQ-treated group (86 people) vs -2.3 in the placebo group (88 people).



Rapid improvements in daily living

In the 12-week clinical trial, patients taking ZILBRYSQ experienced significant improvement in activities of daily living such as breathing, talking, swallowing, and being able to rise from a chair.* Individual results may vary, and not all people taking ZILBRYSQ will experience improvements.

Some patients also saw improvements in gMG symptoms **as early as Week 1.**

*As determined by improvement in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score from baseline on Week 12 of the study; -4.4 points in the ZILBRYSQ-treated group (86 people) vs -2.3 in the placebo group (88 people).



gMG treatment in your hands

ZILBRYSQ is self-administered and can be injected in seconds, at home or on the go.

The most common side effects of ZILBRYSQ include injection site reactions, upper respiratory tract infections, and diarrhea.

Important Safety Information Including Boxed Warning

Before taking ZILBRYSQ, tell your healthcare provider about all of your medical conditions, including if you have an infection or fever, 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.

100% of participants who completed this clinical trial opted to take ZILBRYSQ in an additional long-term study.

166 participants completed the ZILBRYSQ clinical trial.

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More about ZILBRYSQ

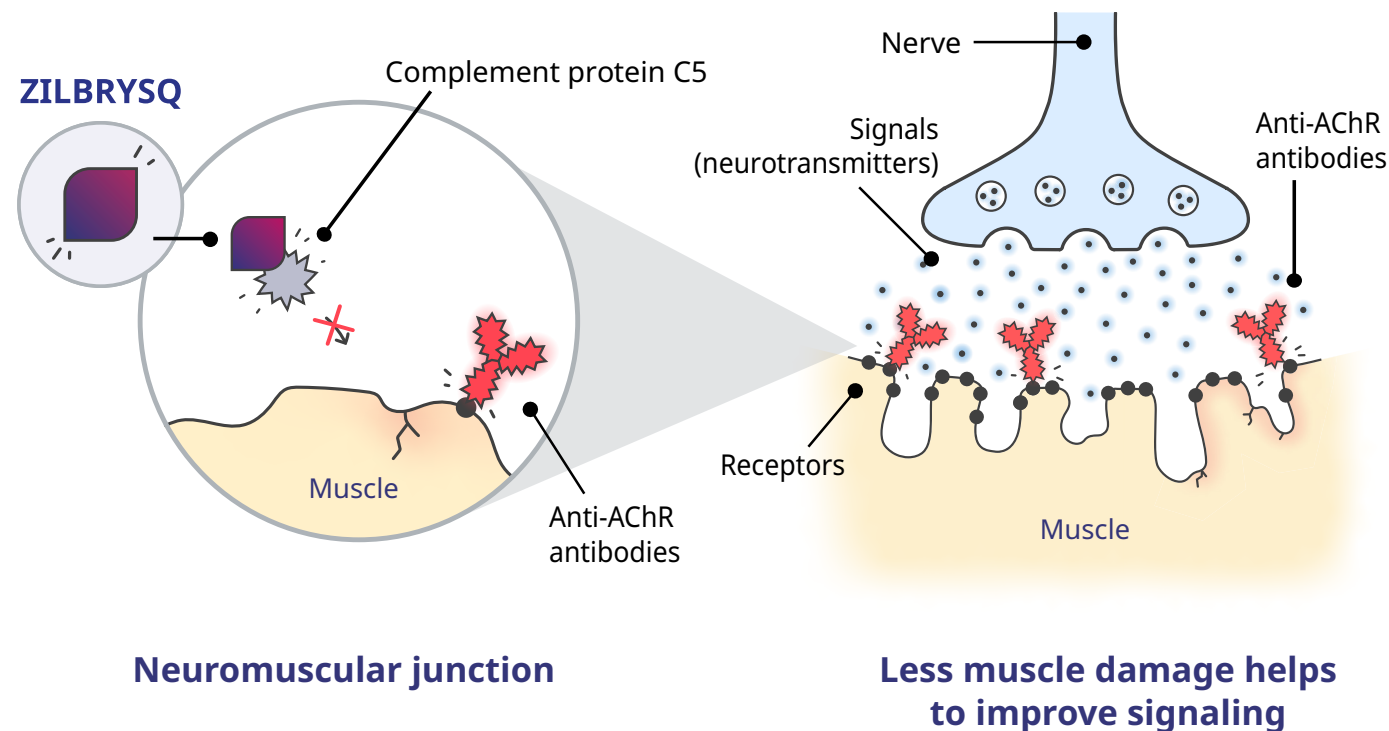
ZILBRYSQ blocks C5, a specific complement protein involved in muscle cell damage

This muscle cell damage can interrupt the signals between nerves and muscles, which is a known cause of gMG symptoms.

By reducing the cause of the muscle cell damage, ZILBRYSQ can help improve those signals between nerves and muscles.*

*The exact mechanism by which ZILBRYSQ works in gMG is unknown.

ZILBRYSQ blocks C5 to help reduce damage



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Self-administer ZILBRYSQ at home or on the go*

ZILBRYSQ comes in a portable, ready-to-use prefilled syringe.

It is a once-daily, subcutaneous (under the skin, not in the muscle) injection that can be self-administered at home or on the go once you or your caregiver receives proper training from your healthcare provider.

*You or your caregiver will receive training from your healthcare provider on the right way to prepare and inject ZILBRYSQ.



The color of the syringe plunger may vary based on the dosage you have been prescribed.

With ZILBRYSQ, there's no need to go to an infusion center or doctor's office to receive treatment. ZILBRYSQ is self-administered and can be injected in about the time it takes to read this sentence.

Important Safety Information Including Boxed Warning

ZILBRYSQ is only available through a program called the ZILBRYSQ REMS. Do not use ZILBRYSQ if you have a *Neisseria meningitidis* infection. ZILBRYSQ may also increase the risk of other types of serious infections. Call your healthcare provider right away if you have new signs or symptoms of infection.



Significant improvements in the activities of daily living

ZILBRYSQ 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 Week 12 of the study; -4.4 points in the ZILBRYSQ-treated group (86 people) vs -2.3 in the placebo group (88 people).

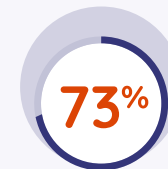
These results were measured using the Myasthenia Gravis Activities of Daily Living scale (MG-ADL).

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.†



Rapid improvements in daily living

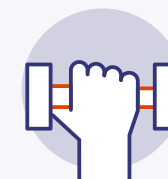
ZILBRYSQ was shown to significantly improve activities of daily living at 12 weeks. Improvements were seen in some participants as early as Week 1.†



More than 7 in 10 participants responded to treatment

Among clinical trial participants receiving ZILBRYSQ, a majority experienced an improvement in symptoms.‡

‡73% (63 out of 86 people) in the 0.3 mg/kg group compared to 46% (40 out of 88 people) in the placebo group, as determined by improvement in MG-ADL score from baseline without rescue therapy on Week 12 of the study. Response was defined as at least a 3-point improvement in MG-ADL score from baseline without rescue therapy by Week 12.



Nearly 6 in 10 participants saw improvement in muscle strength

58% (50 out of 86 people) of clinical trial participants receiving ZILBRYSQ experienced reduced muscle weakness at 12 weeks, improving their physical functions.§

§Compared to 33% of people taking placebo, as determined by the Quantitative MG (QMG) total score. The QMG score assesses muscle weakness based on 13 functions, including looking side-to-side, looking upward, facial movements, swallowing, speaking, outstretching right arm, outstretching left arm, vital capacity, right hand grip, left hand grip, lifting head, outstretching right leg, and outstretching left leg. Response was defined as having at least a 5-point decrease in QMG score at Week 12 without rescue therapy.

†Individual results may vary and not all people taking ZILBRYSQ will experience improvements.

Important Safety Information Including Boxed Warning

ZILBRYSQ is a medicine that affects part of your immune system. ZILBRYSQ may lower the ability of your immune system to fight certain infections. ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may become life-threatening or fatal if not recognized and treated early. You must complete or update two types of meningococcal vaccines at least 2 weeks before your first dose of ZILBRYSQ.

Safety of ZILBRYSQ in the clinical trial

The following side effects were experienced by 5% or more participants taking ZILBRYSQ and more frequently than those on placebo:

Side effect	ZILBRYSQ (86 participants)	Placebo (88 participants)
Injection site reactions	29%	16%
Upper respiratory tract infections	14%	7%
Diarrhea	11%	2%
Urinary tract infection	8%	5%
Nausea or vomiting	8%	7%
Lipase increased	7%	0%
Amylase increased	5%	1%

Additional safety information

- ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections
- For more information about meningococcal vaccinations, see page 12

- ZILBRYSQ may also increase the risk of other types of serious infections
- ZILBRYSQ may increase your chance of getting *Streptococcus pneumoniae* and *Haemophilus influenzae* type b. Your healthcare provider will tell you if you should receive the *Streptococcus pneumoniae* and *Haemophilus influenzae* type b vaccinations
- Certain people may have an increased risk of gonorrhea infection. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and about regular testing
- Pancreatitis and pancreatic cysts have happened in people who use ZILBRYSQ. Your healthcare provider will do blood tests to check your pancreas before you start treatment with ZILBRYSQ
- No participants taking ZILBRYSQ stopped treatment due to injection site reaction



To report any suspected side effects or adverse reactions, contact UCB, Inc. at 844-599-2273 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

ZILBRYSQ REMS and vaccination requirements

ZILBRYSQ is a medicine that affects part of your immune system

- ZILBRYSQ may lower the ability of your immune system to fight certain infections
- ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may become life-threatening or fatal if not recognized and treated early

ZILBRYSQ is only available through a program called the ZILBRYSQ REMS (Risk Evaluation and Mitigation Strategy)

To learn more about the ZILBRYSQ REMS, visit ZILBRYSQREMS.com.

Before starting treatment with ZILBRYSQ, you must complete required meningococcal vaccinations

If you have had meningococcal vaccinations in the past, your doctor may decide that you need to get revaccinated.



Talk to your healthcare provider about which vaccinations are needed to begin treatment with ZILBRYSQ.

The pharmacy for ZILBRYSQ, PANTHERx Rare, is available to help you with access to REMS required vaccines



Vaccination status and tracking

- Once you receive your ZILBRYSQ prescription, PANTHERx Rare may contact your doctor for your vaccination history (if not provided already)
- If vaccination is required, PANTHERx Rare will track timing for vaccination and boosters to communicate scheduled doses with you and your doctor, as appropriate



Vaccination support

To support you, PANTHERx Rare will:

- Monitor all aspects of your treatment journey as it relates to accessing vaccinations required by the REMS requirements
- Help you access vaccinations by identifying local resources (retail/community pharmacies, or local health departments) within your geographic location that can administer required vaccinations
- Follow up with your doctor to document vaccinations received in your medical records as appropriate

ZILBRYSQ REMS and vaccination requirements (continued)

Before you can receive ZILBRYSQ, your doctor must:



Counsel you about the risk of meningococcal infection



Make sure you have completed your meningococcal vaccinations at least 2 weeks prior to your first dose of ZILBRYSQ



Provide a prescription for antibiotics if you have not completed or updated vaccinations for meningococcal infections at least 2 weeks before your first ZILBRYSQ dose and must start treatment right away

Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:

- headache with nausea or vomiting
- headache and fever
- headache with a stiff neck or stiff back
- fever
- fever and a rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card that explains the risk of meningococcal infection

Carry your card with you at all times during treatment and for 2 months after your last ZILBRYSQ dose.

- Your risk of meningococcal infection may continue for several weeks after your last dose of ZILBRYSQ
- It is important to show the card to any healthcare provider or nurse who treats you. The information will help them diagnose and treat you quickly



Your doctor will give you a [Patient Guide](#) that explains the symptoms and risk of meningococcal infection.

Important Safety Information Including Boxed Warning

What is the most important information I should know about ZILBRYSQ?

ZILBRYSQ is a medicine that affects part of your immune system. ZILBRYSQ may lower the ability of your immune system to fight certain infections.

- ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may become life-threatening or fatal if not recognized and treated early.
 - You must complete or update two types of meningococcal vaccines (for both serogroup B infections and serogroup A, C, W, and Y infections) at least 2 weeks before your first dose of ZILBRYSQ if you have not already had these vaccines.
 - If your healthcare provider decided that urgent treatment with ZILBRYSQ is needed, you should receive meningococcal vaccination(s) as soon as possible.
 - If you have not completed or updated vaccinations for meningococcal infections at least 2 weeks before your first ZILBRYSQ dose and ZILBRYSQ therapy must be started right away, you must also receive antibiotics.
 - If you had a meningococcal vaccine in the past, you might need additional vaccination before starting ZILBRYSQ. Your healthcare provider will decide if you need additional meningococcal vaccination.
 - Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:**
 - headache with nausea or vomiting
 - headache and fever
 - headache with a stiff neck or stiff back
 - fever
 - fever and a rash
 - confusion
 - muscle aches with flu-like symptoms
 - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of meningococcal infection. Carry it with you at all times during treatment and for 2 months after your last ZILBRYSQ dose. Your risk of meningococcal infection may continue for several weeks after your last dose of ZILBRYSQ. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

ZILBRYSQ is only available through a program called the ZILBRYSQ REMS. Before you can receive ZILBRYSQ, your healthcare provider must:

- enroll in the ZILBRYSQ REMS.
- counsel you about the risk of meningococcal infection.
- give you the Patient Guide, including information about the signs and symptoms of meningococcal infection.
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above.
- make sure that you are vaccinated with two types of meningococcal vaccines and, if needed, get revaccinated with the meningococcal vaccines. Ask your healthcare provider if you are not sure if you need to be revaccinated.

ZILBRYSQ may also increase the risk of other types of serious infections.

- ZILBRYSQ may increase your chance of getting *Streptococcus pneumoniae* and *Haemophilus influenzae* type b. Your healthcare provider will tell you if you should receive the *Streptococcus pneumoniae* and *Haemophilus influenzae* type b vaccinations.
- Certain people may have an increased risk of gonorrhea infection. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and about regular testing.

Call your healthcare provider right away if you have new signs or symptoms of infection.



Important Safety Information Including Boxed Warning (continued)

Who should not use ZILBRYSQ?

Do not use ZILBRYSQ if you have a *Neisseria meningitidis* infection.

Before you use ZILBRYSQ, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- are pregnant or plan to become pregnant. It is not known if ZILBRYSQ will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZILBRYSQ passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use ZILBRYSQ.

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



What are the possible side effects of ZILBRYSQ?

ZILBRYSQ may cause serious side effects, including:

- See “What is the most important information I should know about ZILBRYSQ?”
- **Inflammation of the pancreas (pancreatitis) and other pancreatic problems.** Pancreatitis and pancreatic cysts have happened in people who use ZILBRYSQ. Your healthcare provider will do blood tests to check your pancreas before you start treatment with ZILBRYSQ.

- **Call your healthcare provider right away** if you have pain in your stomach area (abdomen) that will not go away. Your healthcare provider will tell you if you should stop using ZILBRYSQ. The pain may be severe or felt going from your abdomen to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

The most common side effects of ZILBRYSQ include:

- injection site reactions.
- upper respiratory tract infections.
- diarrhea.

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

See the detailed Instructions for Use that comes with ZILBRYSQ for information on how to prepare and inject a dose of ZILBRYSQ, and how to properly throw away (dispose of) used ZILBRYSQ prefilled syringes.

What is ZILBRYSQ?

- ZILBRYSQ is a prescription medicine used to treat adults with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- It is not known if ZILBRYSQ is safe and effective in children.

Please see the full [Prescribing Information](#) and [Medication Guide](#) for ZILBRYSQ, including the Boxed Warning regarding serious meningococcal infections. Please see the [Instructions for Use](#) for the ZILBRYSQ Single-Dose Prefilled Syringe. Talk to your healthcare provider about your condition or your treatment. For more information, go to www.ZILBRYSQ.com or call 1-844-599-2273.

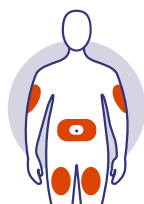
How to use ZILBRYSQ



Always take ZILBRYSQ as prescribed. Each prefilled syringe is for single-use only. Discard the prefilled syringe after each use. Do not reuse. If you miss your ZILBRYSQ dose, inject a dose as soon as possible. Then, inject your next dose at your regular scheduled time. Do not inject more than 1 dose each day.



Pick a time that works for you to inject your daily dose. It's important to inject your daily dose around the same time each day.



Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is at least 1 inch from the spot you used before. **Do not** inject ZILBRYSQ into an area that is red, tender, bruised, swollen, hard or that has scars or stretch marks.

More than

8 out of 10



More than 8 out of 10 people said they were confident in administering ZILBRYSQ.*

*Based on a Self-Injection Assessment Questionnaire (SIAQ) of 63 people studied to understand the self-injection experience.

The most common side effects of ZILBRYSQ include injection site reactions, upper respiratory tract infections, and diarrhea.

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(zilucoplan) Injection

Please see full Important Safety Information on pages 16-19 and [Medication Guide](#).



ZILBRYSQ storage instructions

Do's

- ✓ Always store ZILBRYSQ in the original carton
- ✓ Keep ZILBRYSQ refrigerated
- OR
- ✓ Store at room temperature for a single period of up to 3 months[†]

Don'ts

- ✗ Don't place ZILBRYSQ back in the refrigerator after storing at room temperature
- ✗ Don't use ZILBRYSQ if it has not been used within 3 months of storing at room temperature
- ✗ Don't use ZILBRYSQ if the expiration date on the carton has passed

[†]Store ZILBRYSQ in a refrigerator between 36°F and 46°F (2°C to 8°C) until the expiration date on the carton. Do not freeze ZILBRYSQ.

[‡]Before injecting ZILBRYSQ, let the prefilled syringe warm up to room temperature (up to 86°F [30°C]), on a clean flat surface **for 30 to 45 minutes**. Do not warm the ZILBRYSQ prefilled syringe in any other way (for example in a microwave, in hot water, or in direct sunlight). Prior to dispensing by the pharmacy, store ZILBRYSQ prefilled syringes refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton until dispensing.

Keep ZILBRYSQ prefilled syringes and all medicines out of the reach of children.



For full instructions on self-administering ZILBRYSQ, download the digital [Instructions For Use \(IFU\)](#). Speak to your doctor if you have any questions.

Important Safety Information Including Boxed Warning

Pancreatitis and pancreatic cysts have happened in people who use ZILBRYSQ. Call your healthcare provider right away if you have pain in your stomach area (abdomen) that will not go away.

Helpful resources

For connection, inspiration, and support

Visit [ZILBRYSQ.com](https://www.zilbrysq.com) for educational resources, personalized support, and downloadable tools designed to help you make the most of your ZILBRYSQ treatment.



For further support, you can connect with others in the gMG community at the following sites:



Interested in learning about another treatment for generalized myasthenia gravis? [Explore other treatment options.](#)

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Please see full Important Safety Information on pages 16-19 and [Medication Guide](#).



Personalized support, made for you

ONWARD[™] was created with the help of rare disease patients and healthcare providers. Once you receive your ZILBRYSQ prescription, you can begin a support experience that is there for you every step of the way.

ONWARD provides:



A medically trained ONWARD Care Coordinator personally assigned to you.*



Help with reviewing potential financial assistance options.



Tools and resources to help you get started on and continue your prescribed treatment.



Guidance with symptom tracking, refresher injection coaching, and ongoing treatment support.

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



Join the ONWARD support program

Ask your doctor to sign you up.

Or visit www.ucbONWARD.com/ZILBRYSQ.

Or call 1-844-ONWARD-1 (1-844-669-2731) Mon-Fri, 8:00 AM - 8:00 PM ET.

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.

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Ask your doctor about ZILBRYSQ

The **first FDA-approved, self-administered treatment** for adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

Want to learn even more about ZILBRYSQ?

Sign up for emails by visiting ZILBRYSQ.com/sign-up. You will receive:

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

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