

ZILBRYSQ®
(zilucoplan) Injection

Your guide to vaccination requirements when starting ZILBRYSQ

For adults with anti-acetylcholine
receptor (AChR) antibody-positive
**GENERALIZED MYASTHENIA
GRAVIS (gMG)**

Actor Portrayals

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 infections. ZILBRYSQ increases your chance of getting serious meningococcal infections. You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of ZILBRYSQ. If you have not completed your vaccinations or have not been vaccinated and ZILBRYSQ must be started right away, you should receive the required vaccine(s) as soon as possible and receive antibiotics to take for as long as your healthcare provider tells you. **Call your healthcare provider or get emergency medical care right away if you get any signs and symptoms of a meningococcal infection. Do not use ZILBRYSQ if you** have a serious meningococcal infection when you are starting ZILBRYSQ treatment. ZILBRYSQ may also increase the risk of other types of serious infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*. Call your healthcare provider right away if you have new signs or symptoms of infection. 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 4-7 and [Medication Guide](#).

What to know before starting ZILBRYSQ

ZILBRYSQ REMS and vaccinations

You have been prescribed ZILBRYSQ, a prescription medicine used to treat a disease called gMG. ZILBRYSQ is for adults with gMG who are anti-acetylcholine receptor (AChR) antibody positive.

ZILBRYSQ is only available through a restricted program called the ZILBRYSQ REMS (Risk Evaluation and Mitigation Strategy). This means that you must complete or update meningococcal vaccines (for serogroups A, C, W, Y, and B) at least 2 weeks before your first dose of ZILBRYSQ if you have not already had these vaccines.

What does ZILBRYSQ do?

ZILBRYSQ works to block C5, a specific complement protein involved in muscle cell damage, which occurs with gMG.

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

Why are vaccines required with ZILBRYSQ?

The FDA requires a safety program for any medication that blocks C5. By blocking C5, ZILBRYSQ increases your chance of getting serious meningococcal infections, which may quickly become life-threatening or cause death if not recognized and treated early. The goal of the ZILBRYSQ REMS is to reduce the risk of these infections.

How do I complete the vaccinations?

Your healthcare provider will discuss which vaccinations you will need. The following page shows the steps to complete your vaccinations.

When can I start ZILBRYSQ?

You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of ZILBRYSQ.

If you have not completed your meningococcal vaccines and ZILBRYSQ must be started right away, you should receive the required vaccine(s) as soon as possible.

If you have not been vaccinated and ZILBRYSQ must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.



It is important to take your medication as prescribed.

Support at every step of your treatment journey

ONWARD[®], a UCB-sponsored patient support program, can provide you with a dedicated care coordinator to help you know what to expect from your treatment. Once enrolled, you can learn more about coverage and potential financial assistance options that may be available to you.

The ONWARD team works closely with **PANTHERx Rare**, the specialty pharmacy that will dispense your medication and can help facilitate your access to REMS required vaccines prescribed by your healthcare provider.

For more information, call:

ONWARD at 1-844-ONWARD-1 (1-844-669-2731) or PANTHERx Rare at 1-833-418-7760.

ONWARD Care Coordinators do not provide medical advice and will refer you to your healthcare professional for any questions related to your treatment plan. ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.



Steps to take before starting ZILBRYSQ:

1 IDENTIFY your vaccination status

Your healthcare provider can check your vaccination records. PANTHERx Rare may also help by contacting your healthcare provider to document your vaccination history

2 COMPLETE or UPDATE your vaccinations

PANTHERx Rare will monitor all aspects of your patient journey as it relates to accessing vaccines needed for REMS requirements. If needed, they can help identify local resources that can administer the required vaccines

3 CONFIRM completion of vaccinations

Once your vaccination requirements are officially complete, talk to your healthcare provider about when you can begin your treatment

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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 infections.

- ZILBRYSQ increases your chance of getting serious meningococcal infections caused by *Neisseria meningitidis* bacteria. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.
 - You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of ZILBRYSQ.
 - If you have not completed your meningococcal vaccines and ZILBRYSQ must be started right away, you should receive the required vaccine(s) as soon as possible.
 - If you have not been vaccinated and ZILBRYSQ must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
 - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ZILBRYSQ. Your healthcare provider will decide if you need additional meningococcal vaccines.
 - 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:**
 - fever
 - fever and a rash
 - fever with high heart rate
 - headache with nausea or vomiting
 - headache and fever
 - headache with a stiff neck or stiff back
 - confusion
 - eyes sensitive to light
 - muscle aches with flu-like symptoms

Your healthcare provider will give you a Patient Safety Card about the risk of serious 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 Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ZILBRYSQ, your healthcare provider must:

- enroll in the ZILBRYSQ REMS program.
- counsel you about the risk of meningococcal infections.
- 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 against serious infections caused by meningococcal bacteria and that you receive antibiotics if you need to start ZILBRYSQ right away and you are not up to date on your vaccines.

ZILBRYSQ may also increase the risk of other types of serious infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*.

- Certain people may be at risk of serious infections with gonorrhea. 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.



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Important Safety Information Including Boxed Warning (continued)

Who should not use ZILBRYSQ?

- **Do not use ZILBRYSQ if you** have a serious meningococcal infection when you are starting ZILBRYSQ treatment.

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.

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Talk to your healthcare provider about completing or updating your vaccinations at least 2 weeks before your first dose of ZILBRYSQ.

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

Please keep this vaccination card as a record of the meningococcal vaccinations you have received.



Last Name First Name

Date of Birth (MM/DD/YY) Patient Number

This vaccination card is for patient use and is not intended to replace official immunization records.

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Download the [vaccination card](#) to track your progress.

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