

MEDICATION GUIDE

ZILBRYSQ® (ZIL-brisk)
(zilucoplan)

injection, for subcutaneous use

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.

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.

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.

Know the medicines you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use ZILBRYSQ?

See the detailed Instructions for Use that comes with your 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.

- ZILBRYSQ is given as an injection under the skin (for subcutaneous use) in a prefilled syringe. Use ZILBRYSQ exactly as prescribed by your healthcare provider.
- After proper training on how to prepare and inject your ZILBRYSQ syringe, you or your caregiver will inject ZILBRYSQ daily. Your healthcare provider will decide the total daily dose depending on your body weight.
- Each prefilled syringe is for single-use only. Throw away the prefilled syringe after each use. Do not reuse.
- Your daily dose of ZILBRYSQ should be injected at about the same time each day.

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. Call your healthcare provider if you are not sure what to do.

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.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZILBRYSQ?

- ZILBRYSQ prefilled syringes may be stored in the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date on the carton. Do not freeze ZILBRYSQ. Keep the prefilled syringes in the original carton until ready for use to protect from light.
- ZILBRYSQ prefilled syringes may be stored at room temperature up to 86°F (30°C) in the original carton to protect them from light for a single period of up to 3 months. Write the date you removed the prefilled syringes from the refrigerator in the space provided on the carton. After ZILBRYSQ prefilled syringes have been stored at room temperature, do not place them back in the refrigerator and throw them away if not used within the 3-month period or if the expiration date has passed, whichever occurs first.
- Throw away any unused portion.

Keep ZILBRYSQ prefilled syringes and all medicines out of the reach of children.**General information about the safe and effective use of ZILBRYSQ.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZILBRYSQ for a condition for which it was not prescribed. Do not give ZILBRYSQ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZILBRYSQ that is written for health professionals.

What are the ingredients in ZILBRYSQ?

Active ingredient: zilucoplan

Inactive ingredients: dibasic sodium phosphate, anhydrous, monobasic sodium phosphate, monohydrate, sodium chloride, and water for injection.

Manufactured for UCB, Inc., Smyrna, GA 30080

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For more information, visit www.ZILBRYSQ.com or call 1-844-599-2273.