PATIENT/CARER GUIDE

ZILBRYSQ® (zilucoplan)

What you need to know about zilucoplan

This is a guide for patients who use zilucoplan and for those who care for them. It contains important safety information about the use of zilucoplan.

What is zilucoplan?

Zilucoplan is a prescription medicine that is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. It comes in pre-filled syringes that are each made to give a single daily dose. It is injected under the skin.

Zilucoplan affects part of the immune system and can lower its ability to fight certain infections.

What are the key risks of zilucoplan?

Zilucoplan may increase your chance of getting a meningococcal infection. This can be an infection of the linings of the brain and spinal cord called meningitis. It can also be an infection of the blood called septicaemia. This infection may quickly become life-threatening or fatal if not recognised and treated early.

Call your doctor or seek emergency care right away if you have any signs or symptoms of meningococcal infection:

- Headache with any of these other symptoms:
  — nausea or vomiting — stiff neck — stiff back — fever
- Fever with or without rash
- Sensitivity of eyes to light
- Confusion or drowsiness
- Muscle aches with flu-like symptoms

Date of Preparation: August 2024
Approval by MHRA: July 2024

GB-ZL-2300012

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Why do I need to get vaccinated?

It is important that you get vaccinated to lower the risk of getting a meningococcal infection.

- You will need to receive meningococcal vaccines **at least 2 weeks before** the first dose of zilucoplan.
- Your doctor will review your vaccine history and let you know which vaccines you need.
- Vaccinations lower the risk of meningococcal infection but do not eliminate the risk completely. Unfortunately, these infections may still occur. You will still need to watch for signs and symptoms.

In some cases, your doctor may decide that zilucoplan must be started in less than 2 weeks after meningococcal vaccination. If that's the case for you:

- You must still get your meningococcal vaccines as soon as possible.
- You will also need to take antibiotics until 2 weeks after your first vaccine dose.
- Your doctor will select an antibiotic for you to take.

If you have already had meningococcal vaccines, discuss this with your doctor. You might need to get additional doses of meningococcal vaccines before you start zilucoplan.

During treatment with zilucoplan, you may also need additional doses of meningococcal vaccines. It is important to discuss this with your doctor to ensure that your vaccination status is always up to date throughout treatment with zilucoplan.

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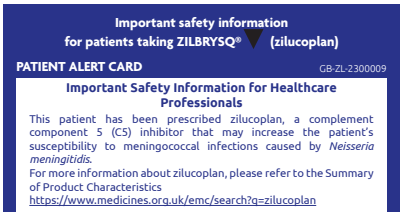
IMPORTANT INFORMATION

A controlled access program is in place to ensure that only patients who have been vaccinated against meningococcal infection will be able to receive zilucoplan. You will need to get vaccinated, and your doctor will give you a Pharmacist Information Letter. Give the letter to your pharmacist. This letter provides important instructions for ordering zilucoplan, including your patient ID. The pharmacist will be unable to order zilucoplan if they do not receive this letter

Patient Alert Card


Important safety information
for patients taking ZILBRYSQ® (zilucoplan)

PATIENT ALERT CARD GB-ZL-2300009

Important Safety Information for Healthcare Professionals

This patient has been prescribed zilucoplan, a complement component 5 (C5) inhibitor that may increase the patient's susceptibility to meningococcal infections caused by *Neisseria meningitidis*.

For more information about zilucoplan, please refer to the Summary of Product Characteristics
https://www.medicines.org.uk/emc/search?q=zilucoplan

Your doctor will give you a Patient Alert Card if you will be taking zilucoplan.

- The card includes important information about your medical treatment.
- Keep this card with you at all times during treatment and for 2 months after your last zilucoplan dose. Your risk of meningococcal infection may continue for several weeks after your last dose of zilucoplan.

Show the **Patient Alert Card** to any healthcare professional you go to for treatment.

- The card lets them know about your zilucoplan treatment.
- It will help them diagnose and treat a possible meningococcal infection promptly.

Call your doctor or seek emergency care right away for any symptoms of meningococcal infection.

Your doctor will give you a **Pharmacist Information Letter**.

Give this letter to your pharmacist. This letter provides important instructions for ordering zilucoplan including your patient ID. The pharmacist will be unable to order zilucoplan if they do not receive this letter.

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How to take zilucoplan

Your healthcare professional will show you how to inject zilucoplan. **Do not** inject yourself or someone else until you have been shown how to inject zilucoplan correctly.

Zilucoplan is injected under the skin. Always administer your daily dose at approximately the same time every day. Choose an injection site from the following areas:

- The stomach (abdomen), except for the 5 cm/2-inch area around the belly button (navel)
- The front of the thighs
- The back of the upper arms (only if someone else is giving you the injection)

Choose a different site for each injection. Please refer to the patient information leaflet for a diagram of injection sites.

Do not inject zilucoplan into an area that is tender, red, bruised, hard or that has scars or stretch marks.

If you miss a dose, please contact your doctor immediately for advice. If you didn't inject the dose at the usual time, please inject as soon as you realise it and then continue with the dosing at the normal time the next day. Do not administer more than one dose per day.

You can fill out the chart located on the inside flap of the packaging to note the date of your injection and the specific injection site.

Please read ALL the Instructions for Use in the patient information leaflet before you inject zilucoplan https://www.medicines.org.uk/emc/search?q=zilucoplan.

Reporting side effects

▼ This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- ***the Yellow Card website www.mhra.gov.uk/yellowcard***
- ***the free Yellow Card app available from the Apple App Store or Google Play Store***

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events should also be reported to UCB Pharma Ltd via UCBCares® on 0800 279 3177 (freephone) or by email UCBCares.UK@ucb.com

Data privacy

UCB processes personal data of patients receiving zilucoplan for the purposes of management and reduction of the risks linked to the use of zilucoplan without appropriate vaccination. See our Patient Privacy Policy for details about the processing of your personal data, your rights and how to exercise them. Patient Privacy Policy is available at https://www.ucb.com/General-Patient-Privacy-Notice or by requesting it from UCB at UCBCares.UK@ucb.com or on 0800 279 3177 (freephone)

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