

Package leaflet: Information for the patient

Zilbrysq 16.6 mg solution for injection in pre-filled syringe
Zilbrysq 23 mg solution for injection in pre-filled syringe
Zilbrysq 32.4 mg solution for injection in pre-filled syringe
zilucoplan

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zilbrysq is and what it is used for
2. What you need to know before you use Zilbrysq
3. How to use Zilbrysq
4. Possible side effects
5. How to store Zilbrysq
6. Contents of the pack and other information

1. What Zilbrysq is and what it is used for

Zilbrysq contains the active substance zilucoplan. Zilucoplan attaches to and blocks a protein in the body known as the C5 complement protein, which is a part of the immune system (the body's natural defences). By blocking this protein, zilucoplan prevents the body's immune system from attacking and destroying connections between nerves and muscles, thereby improving symptoms of the disease and reduce their impact on daily activities.

Zilbrysq is used together with standard therapy to treat adult patients with generalised myasthenia gravis (gMG), an autoimmune disease that causes muscle weakness. It is used in adults whose immune system produces antibodies against a protein called the acetylcholine receptor, located on muscle cells. In patients with gMG, the muscles can be attacked and damaged by the immune system, which can lead to profound muscle weakness, impaired mobility, shortness of breath, extreme tiredness, difficulties swallowing and markedly impaired activities of daily living.

2. What you need to know before you use Zilbrysq

Do not use Zilbrysq

- if you are allergic to zilucoplan or any of the other ingredients of this medicine (listed in section 6).
- if you have not been vaccinated against meningococcal infection. See warnings and precautions section.
- if you have a meningococcal infection.

Warnings and precautions

Meningococcal and other *Neisseria* infections alert

As Zilbrysq inhibits the body's natural defences against infection, its use may increase your risk of infections caused by *Neisseria meningitidis*, such as meningococcal infection (severe infection of the linings of the brain and spinal cord and/or an infection of the blood) and also of other infections caused by *Neisseria* bacteria, such as gonorrhoea.

Consult your doctor before you take Zilbrysq to be sure that you receive vaccination against *Neisseria meningitidis*, an organism that causes meningococcal infection, at least 2 weeks before beginning therapy. If you cannot be vaccinated 2 weeks beforehand, your doctor will prescribe antibiotics to reduce the risk of infection until 2 weeks after you have received your first vaccine dose. Ensure that your meningococcal vaccinations are up to date. You should be aware that vaccination may not always prevent this type of infection.

If you are at risk of gonorrhoea (sexually transmitted bacterial infection), ask your doctor for advice before using this medicine.

Meningococcal infection symptoms

Because of the importance of rapidly identifying and treating meningococcal infections in patients who receive Zilbrysq, you will be provided a card to carry with you at all times, listing specific signs and symptoms of possible meningococcal infection. It also contains information for healthcare professionals that may not be familiar with Zilbrysq. This card is named "patient alert card". You will also be provided a patient/carer guide which contains further information on Zilbrysq.

If you experience any of the following symptoms, you should immediately inform your doctor:

- Headache with additional symptoms such as nausea (feeling sick), vomiting, fever and stiff neck or back
- Fever with or without a rash
- Eyes sensitive to light
- Confusion / drowsiness
- Muscle pain with flu-like symptoms

Treatment for meningococcal infection while travelling

If you are travelling in a region where you are unable to contact your doctor or will temporarily be unable to receive medical treatment, your doctor may prescribe an antibiotic against *Neisseria meningitidis* to bring with you. If you experience any of the symptoms described above, you should take the antibiotic treatment as prescribed. You should bear in mind that you should see a doctor as soon as possible, even if you feel better after having taken the antibiotic treatment.

Children and adolescents

Do not give this medicine to children below the age of 18 years. Zilbrysq has not been studied in this age group.

Other medicines and Zilbrysq

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is uncertainty about the effects that Zilbrysq can have to your unborn child, so do not use this medicine if you are pregnant or think that you may be pregnant unless your doctor specifically recommends it.

It is not known whether Zilbrysq passes into human milk. There may be a risk to newborns/infants.

A decision must be made whether to discontinue breast feeding or to discontinue Zilbrysq therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman.

Driving and using machines

Zilbrysq is not likely to affect your ability to drive or use machines.

Zilbrysq contains sodium

This medicine contains less than 23 mg of sodium per pre-filled syringe, that is to say essentially 'sodium-free'.

3. How to use Zilbrysq

At least 2 weeks before you start treatment with Zilbrysq, your doctor will give you a vaccine against meningococcal infection if you have not previously received it or if your vaccination is outdated. If you cannot be vaccinated at least 2 weeks before you start treatment with Zilbrysq, your doctor will prescribe antibiotics to reduce the risk of infection until 2 weeks after you have received your first vaccine dose.

Before you start treatment you should also discuss with your doctor if you need any other vaccines.

After suitable training, your doctor will allow you to inject Zilbrysq yourself. Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The dose you receive will depend on your bodyweight. Always administer your daily dose at approximately the same time of the day.

The following table indicates the total daily dose of Zilbrysq according to your body weight:

Body weight	Dose	Number of pre-filled syringes by colour
< 56 kg	16.6 mg	1 (Rubine red)
≥ 56 to < 77 kg	23 mg	1 (Orange)
≥ 77 kg	32.4 mg	1 (Dark blue)

How Zilbrysq is given

You and your doctor or nurse will decide if you can inject this medicine yourself. Do not self-inject this medicine unless you have been trained by a healthcare professional. Another person may also give your injections after they have been trained.

Zilbrysq will be given as a subcutaneous injection (an injection under the skin) once a day. It can be injected into the stomach area, the front of the thighs or the back of the upper arms. Injections in the back of the upper arms should only be given by another person. The injection location should be rotated and should not be given into areas where the skin is tender, bruised, red or hard or where the skin has scars or stretch marks.

It is important that you read the instructions for use at the end of the package leaflet for detailed information on how to use Zilbrysq.

If you use more Zilbrysq than you should

If you suspect that you have accidentally received a higher dose of Zilbrysq than prescribed, please contact your doctor for advice.

If you forget to use Zilbrysq

If you didn't inject the dose at the usual time or missed a dose, please inject as soon as you realize it and then continue with the dosing at the normal time the next day. Do not administer more than one dose per day.

If you stop using Zilbrysq

Interrupting or stopping treatment with Zilbrysq may cause your symptoms to come back. Please speak to your doctor before stopping Zilbrysq. Your doctor will discuss the possible side effects and risks with you. Your doctor may also want to monitor you closely.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)

- Injection site reactions, such as bruising, pain, itching and forming of a lump.
- Nose and throat infections.

Common (may affect up to 1 in 10 people)

- Diarrhoea
- Increased pancreas enzymes (amylase, lipase) seen in blood test.
- Morphoea (condition that causes localized discolored and hardened areas of the skin).

Uncommon (may affect up to 1 in 100 people)

- Increased of eosinophils (a type of white blood cell), seen in blood test.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zilbrysq

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the syringe label and outer carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C-8 °C).

Do not freeze.

Keep the pre-filled syringe in the outer carton in order to protect from light.

You may store the Zilbrysq pre-filled syringe at room temperature in the original carton up to 30 °C for only one single period of up to 3 months. Once Zilbrysq has been removed from the refrigerator, it should not be placed back into the refrigerator. The product must be discarded if not used within 3 months or when the expiry date is reached, whichever occurs first.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zilbrysq contains

- The active substance is: zilucoplan.
- The other ingredients are: sodium dihydrogen phosphate monohydrate, disodium phosphate (anhydrous), sodium chloride, water for injections (see section 2 Zilbrysq contains sodium).

What Zilbrysq looks like and contents of the pack

Zilbrysq is a solution for injection in pre-filled syringe (injection) and is a clear to slightly opalescent and colourless solution, free of visible particles.

Zilbrysq 16.6 mg solution for injection in pre-filled syringe

Each pre-filled syringe with rubine red plunger contains zilucoplan sodium equivalent to 16.6 mg zilucoplan in 0.416 mL.

Zilbrysq 23 mg solution for injection in pre-filled syringe

Each pre-filled syringe with orange plunger contains zilucoplan sodium equivalent to 23 mg zilucoplan in 0.574 mL.

Zilbrysq 32.4 mg solution for injection in pre-filled syringe

Each pre-filled syringe with dark blue plunger contains zilucoplan sodium equivalent to 32.4 mg zilucoplan in 0.810 mL.

Pack size of 7 pre-filled syringes for 16.6 mg, 23 mg and 32.4 mg solution for injection.
Multipack containing 28 (4 packs of 7) pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom

Manufacturer

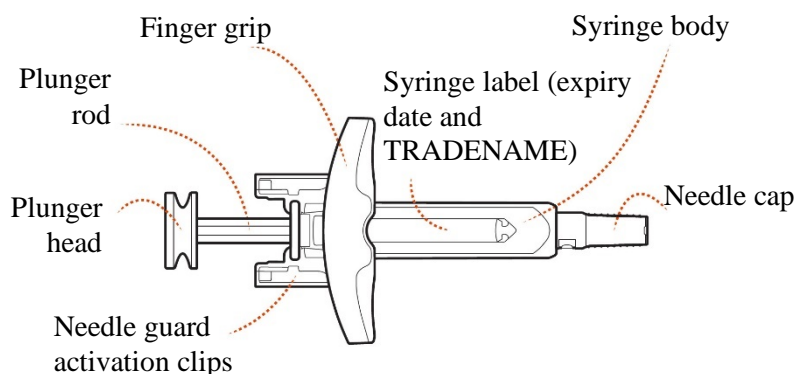
UCB Pharma S.A., Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium

This leaflet was last revised in November 2023.

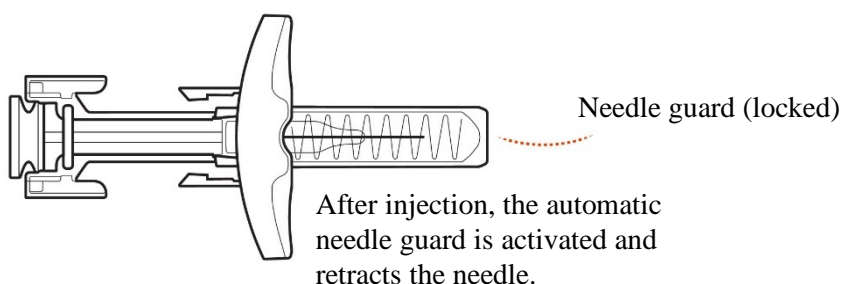
Instructions for Use for Zilbrysq solution for injection in pre-filled syringe

Read ALL the instructions below before you use Zilbrysq

Before use



After use



Important information:

- Your healthcare professional should show you how to prepare and inject Zilbrysq properly before you use it for the first time.
- Call your healthcare professional if you or your caregiver have any questions about how to inject Zilbrysq correctly.

Do not use, and return this medicine to the pharmacy:

- if the pre-filled syringe has been dropped

Follow the steps below each time you use Zilbrysq

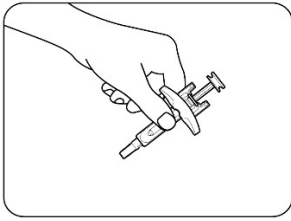
1. Step 1: Setting up your injection

- a) **If the pre-filled syringes are stored in the refrigerator: for a more comfortable injection:** Take 1 Zilbrysq pre-filled syringe out of the refrigerator and let it sit on a clean, flat surface at room temperature for **30 to 45 minutes before injecting**. Do not warm in any other way. Put the rest of the carton back in the refrigerator and proceed to Step b) below.

If the pre-filled syringes are stored at room temperature: Take 1 Zilbrysq pre-filled syringe out of the carton. Any remaining syringes from the carton should not be placed in the refrigerator once stored at room temperature.

When removing one syringe from the outer carton, grasp the body of the syringe (Figures A). **Do not** touch the plunger rod and the needle cap. **Do not** touch the needle guard activation clips at any time because this can cause the premature activation of the needle guard.

Figure A



b) Place the following items on a clean flat, well-lit surface, like a table

- 1 Zilbrysq pre-filled syringe
- 1 alcohol wipe (not supplied)
- 1 cotton ball or gauze pad (not supplied)
- 1 adhesive bandage (not supplied)
- 1 sharps disposal or puncture-resistant container (not supplied). See Step 4 for instructions on throwing away the empty syringe.

c) Inspect the pre-filled syringe

- Check the pre-filled syringe for damage (Figure “Before Use”).
 - **Do not** use if any part of the pre-filled syringe appears to be cracked, leaking, or broken.
 - **Do not** use if the needle cap is cracked or broken, missing or not securely attached to the pre-filled syringe.
- Do not remove the needle cap from the pre-filled syringe until you are ready to inject.
- Do not use if the liquid has ever been frozen (even if thawed), in this case the medicine should not be used.
- Check the expiry date on the syringe label.
- Check the medicine inside the pre-filled syringe. The medicine should be clear to slightly opalescent and colourless. It is normal to see air bubbles in the syringe. **Do not** use if the medicine is cloudy, discoloured, or contains floating particles.
- Check the dose on the label. **Do not** use if the dose does not correspond to your prescription.

2. Step 2: Choose your injection site and prepare your injection

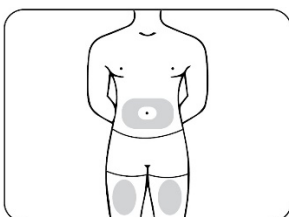
a) Choose your injection site

Choose an injection site from the following areas (Figure B):

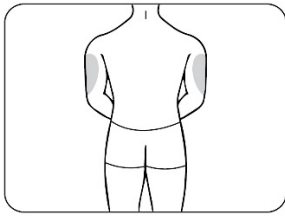
- The stomach (abdomen), except for the 5 cm/2-inch area around the belly button (navel)
- The front of the thighs
- The back of the upper arms

Figure B

- Abdomen and thighs



- The back of the upper arms (only if someone else is giving you the injection)



Choose a different site for each injection. If you want to use the same injection site, make sure it is at least 2.5 cm/1-inch from a spot you used the last time.

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

b) Wash your hands well with soap and water and dry with a clean towel.

c) Prepare your skin

- Clean the injection site using an alcohol wipe.
- Let the skin dry for 10 seconds before injecting.
- **Do not** touch the injection site again before giving your injection.

3. Step 3: Inject Zilbrysq

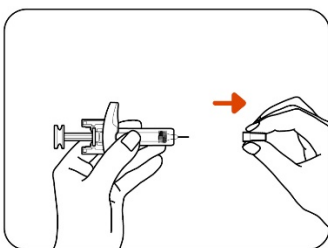
a) Remove the needle cap

Hold the body of the Zilbrysq pre-filled syringe with one hand and pull the needle cap straight off with your other hand (Figure C).

Throw away the needle cap into your household trash or a sharps container (see Step 4).

- **Do not** touch the needle or let it touch anything.
- **Do not** recap the needle at any time to avoid injury.
- **Do not** try to remove any air bubbles from the syringe. Air bubbles will not affect your dose and will not harm you. This is normal. You can continue to take your injection.

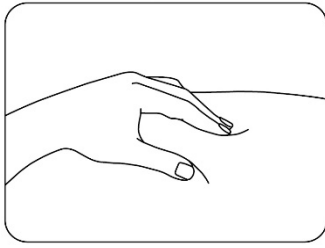
Figure C



b) Pinch your injection site

Use your other hand to pinch the area of cleaned skin and hold it firmly (Figure D).

Figure D

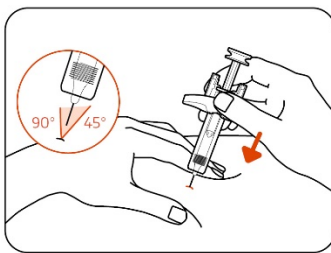


c) Insert the needle

Insert the entire needle into the pinched skin at a 45° to 90° angle. (Figure E).

- **Do not** pull back on the plunger at any time because this could break the syringe
- **Do not** touch the needle guard activation clips

Figure E

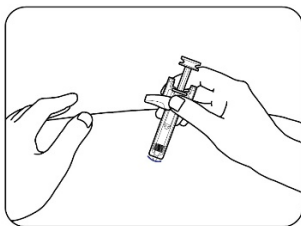


d) Release the pinched skin

When the needle is fully inserted, hold the pre-filled syringe in place and release the pinched skin (Figure F).

- **Do not** reinsert the needle into the skin if the needle is pulled out when releasing the skin because this may bend or break the needle, causing damage to the tissue. If this happens, safely throw away the syringe in a sharps container, and get a new syringe to give the injection.

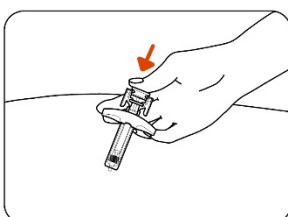
Figure F



e) Inject the medicine

Push the plunger all the way down while holding onto the finger grip to inject all the medicine (Figure G). All the medicine is injected when you cannot push the plunger head any further.

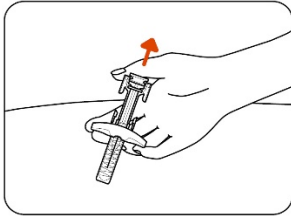
Figure G



f) Release the plunger

Slowly release the plunger by lifting your thumb. After a complete injection, the needle guard will cover the needle and you may hear a click (Figure H).

Figure H



g) Examine the injection site

Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds.

Do not rub the injection site. You may have slight bleeding, this is normal. Apply an adhesive bandage if needed.

Step 4: Throw away the used syringe into a sharps container right away.

Always keep the sharps disposal container out of the reach of children.

Step 5: Record the day of injection and injection site.

Ensure to fill out the chart located on the inside flap of the packaging. Use it to note the date of your injection and the specific injection site.