

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.



This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Zilbrysq?

Zilbrysq contains the active ingredient zilucoplan tetrasodium. Zilbrysq is used to treat generalised myasthenia gravis by blocking the body's inflammatory response. Myasthenia gravis can lead to intense muscle weakness, extreme fatigue, difficulty breathing, difficulty with moving and activities of daily living. For more information, see Section [1. Why am I using Zilbrysq?](#) in the full CMI.

2. What should I know before I use Zilbrysq?

Do not use if you have ever had an allergic reaction to Zilbrysq or any of the ingredients listed at the end of the CMI and if you have not been vaccinated against meningococcal infection and/or have a meningococcal infection.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Zilbrysq?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zilbrysq and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Zilbrysq?

- Your healthcare professional should show you how to prepare and inject Zilbrysq using the pre-filled syringe. Do not inject yourself or someone else until you have been shown how to inject Zilbrysq the right way.
- You and your caregiver should read [4. How do I use Zilbrysq?](#) before each use of Zilbrysq
- 1 pre-filled syringe is injected under the skin daily.

More instructions can be found in Section [4. How do I use Zilbrysq?](#) in the full CMI.

5. What should I know while using Zilbrysq

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Zilbrysq.• Use the product once in one patient only and discard any residue after use.• Be vaccinated against meningococcal infection at least 2 weeks before receiving your first dose of Zilbrysq.
Things you should not do	<ul style="list-style-type: none">• Do not inject yourself with this medicine unless you have been trained by a healthcare professional.• Do not use this medicine after the expiry date which is stated on the label and carton after EXP.
Looking after your medicine	<ul style="list-style-type: none">• Keep this medicine out of the sight and reach of children.• Store in a refrigerator between 2°C – 8°C. Do not freeze. Keep in the original carton to protect from light.• Zilbrysq may be stored at room temperature (up to 30°C) for a single period of a maximum of 3 months with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 3 months or by the expiry date, whichever occurs first. A field for the date is provided on the carton to record the date removed from the refrigerator.

For more information, see Section [5. What should I know while using Zilbrysq?](#) in the full CMI.

6. Are there any side effects?

- Common side effects include: Bruising and pain at site of injection, upper respiratory tract infections (sore throat, blocked nose and headache), diarrhoea and morphoea (condition that causes localised discoloured and hardened areas of the skin).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

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 gonorrhea.

These infections require urgent and appropriate care as they may become rapidly serious or fatal, or lead to major disabilities. It is important to understand the precautions to take to reduce the risk of these infections and what to do if you are worried you may have an infection (see "What I should know before I use Zilbrysq" below or refer to your Patient Alert Card).

- You must be vaccinated against meningococcal infection before starting Zilbrysq.
- If you initiate Zilbrysq treatment less than 2 weeks after receiving a meningococcal vaccine you must take antibiotics until 2 weeks after you have been vaccinated to reduce the risk of meningococcal infection.
- You need to be aware of the signs and symptoms of meningococcal infection (see "What I should know before I use Zilbrysq" below or refer to your Patient Alert Card) and notify your doctor immediately if any of the symptoms occur. If you cannot reach your doctor, go to the Emergency Department at your nearest hospital. Show your Patient Alert Card to any doctor or nurse who treats you.

Zilbrysq®

Active ingredient(s): *zilucoplan tetrasodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Zilbrysq. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Zilbrysq.**

Where to find information in this leaflet:

1. [Why am I using Zilbrysq](#)
7. [What should I know before I use Zilbrysq?](#)
8. [What if I am taking other medicines?](#)
9. [How do I use Zilbrysq?](#)
10. [What should I know while using Zilbrysq?](#)
11. [Are there any side effects?](#)
12. [Product details](#)

1. Why am I using Zilbrysq

Zilbrysq contains the active ingredient zilucoplan tetrasodium. Zilbrysq is a selective immunosuppressant. Zilucoplan binds to and inhibits a specific protein in the body that causes inflammation, preventing your body's systems from attacking and destroying connections between nerves and muscles.

Zilbrysq is used to treat generalised myasthenia gravis by blocking the body's inflammatory response. Myasthenia gravis can lead to intense muscle weakness, extreme fatigue, difficulty breathing, difficulty with moving and activities of daily living.

2. What should I know before I use Zilbrysq?

Warnings

Do not use Zilbrysq if:

- you are allergic to zilucoplan, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- you have not been vaccinated against meningococcal infection
- you have a meningococcal infection.

Check with your doctor if you:

- have any other medical conditions, such as at risk of having gonorrhoea, have an infection, suspicion of infection or a fever
- take any medicines for any other condition
- have not been vaccinated against meningococcal infection
- have been vaccinated against meningococcal infection less than 2 weeks before receiving the first dose of Zilbrysq

Meningococcal and other *Neisseria* infections:

Zilbrysq treatment may reduce your natural resistance to infections with *Neisseria* bacteria, which can cause a meningococcal infection (an infection of the linings of the brain and spinal cord (meningitis) and/or an infection of the blood (septicemia)) and other infections such as gonorrhea.

Consult with your doctor before you use this medicine to be sure that you receive vaccination against *Neisseria meningitidis*, an organism that causes meningococcal infection, at least 2 weeks before beginning therapy, or that you take 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.

If you are at risk of gonorrhoea, ask your doctor or pharmacist for advice before using this medicine.

Meningococcal infection symptoms:

Meningococcal infections may become life-threatening or fatal if not recognised and treated early. Due to the importance of rapidly identifying and treating meningococcal infections in patients who receive Zilbrysq, if you experience any of the following symptoms, you should immediately inform your doctor:

- Headache with additional symptoms such as nausea, 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Zilbrysq is not recommended during pregnancy and in women of childbearing potential not using contraception.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children and adolescents

Zilbrysq is not recommended for children and young people under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Zilbrysq.

4. How do I use Zilbrysq?

How much to take / use

1 pre-filled syringe is injected under the skin daily. Your doctor will prescribe you the recommended dose of Zilbrysq based on your body weight. The following table indicates the total daily dose of Zilbrysq according to body weight:

Body Weight	Dose	Number of pre-filled syringes and colour
from 43 to below 56 kg	16.6 mg	1 rubine red
from 56 to below 77 kg	23 mg	1 orange
from 77 to below 150 kg	32.4 mg	1 dark blue

- There is limited experience with patients below 43 kg and above 150 kg. You should therefore receive the lowest and the highest dose, respectively.
- Follow the instructions provided and use Zilbrysq until your doctor tells you to stop.

When to take / use Zilbrysq

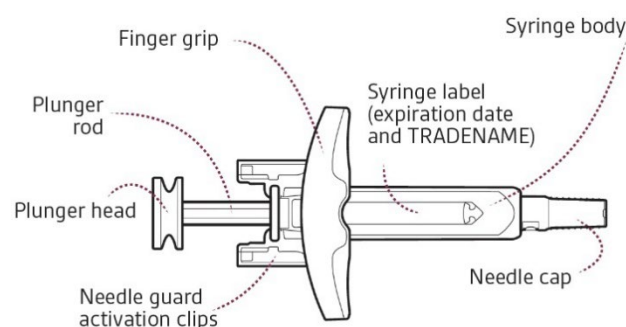
Zilbrysq should be used daily approximately at the same time each day.

How to Inject Zilbrysq pre-filled syringe

- Your doctor should show you how to prepare and inject Zilbrysq pre-filled syringe properly before you use it for the first time.
- You and your caregiver should read this Instruction For Use before initiating treatment with Zilbrysq.
- Call your doctor if you or your caregiver have any questions about how to inject Zilbrysq correctly.

Zilbrysq pre-filled syringe (see figure A):

Before Use



After Use

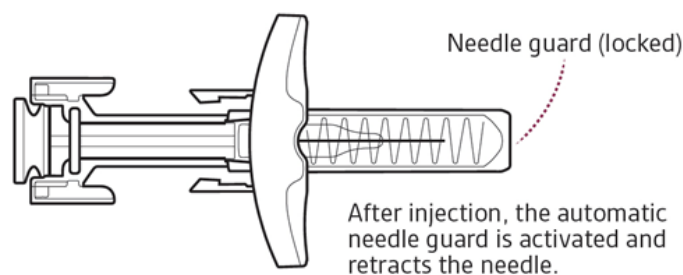


Figure A

Step 1: Setting up for your injection:

a: If the prefilled syringes are stored in the refrigerator:

Take 1 Zilbrysq pre-filled syringe out of 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 (for example in a microwave, in hot water or in direct sunlight). Place the rest of the carton in refrigerator and proceed with 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.

The pre-filled syringe must always be lifted straight up out of the tray (see figure A.1 and A.2)

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

- 1 Zilbrysq pre-filled syringe

You will also need (not included in the carton):

- 1 alcohol wipe
- 1 clean cotton ball
- 1 adhesive bandage
- 1 sharps disposal container

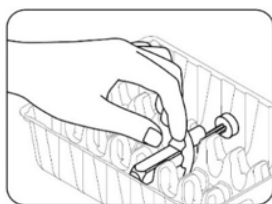


Figure A.1

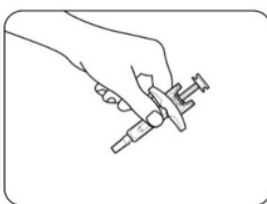


Figure A.2

Do not remove the needle cap from the pre-filled syringe until you are ready to inject.

c: Inspect the pre-filled syringe:

- Check the pre-filled syringe for damage (see Figure B):
 - **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.
- Check if the name Zilbrysq and the expiration date appear on the pre-filled syringe label.

- Check the medicine inside the pre-filled syringe (Figure B). 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 (Figure B). **Do not** use if the dose does not correspond to your prescription.

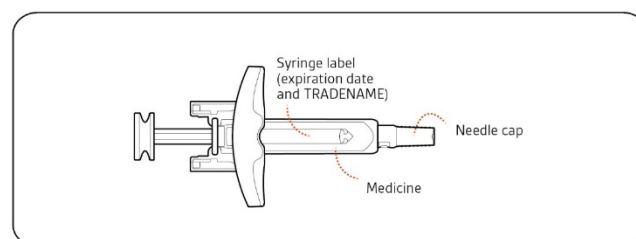


Figure B

Step 2: Choose injection site and prepare your injection

a: Choose your injection site

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

- The stomach (abdomen), except for the 5cm area around the belly button (navel)
- The front of the thighs
- The back of your arm may also be used if a caregiver is giving you the injection

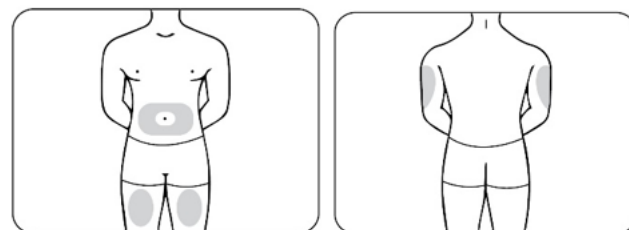


Figure C

- **Do not** inject Zilbrysq into an area that is tender, red, bruised, hard or that has scars or stretch marks.
- 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 from a spot you used the last time.

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

c: Prepare your skin

- Clean the injection site with an alcohol wipe (Figure D).
- Let the skin dry for 10 seconds before injecting.
- **Do not** touch the cleaned area again before injecting.

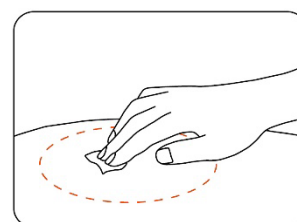


Figure D

Step 3: Inject Zilbrysq

a: Remove the needle cap

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

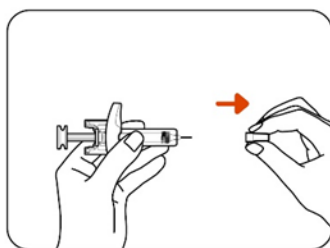


Figure E

b: Pinch your injection site

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

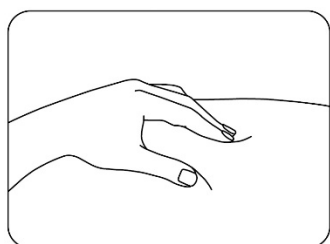


Figure F

c: Insert the needle

Insert the entire needle into the pinched skin at a 45° to 90° angle. When the needle is fully inserted, hold the pre-filled syringe in place (Figure G).

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

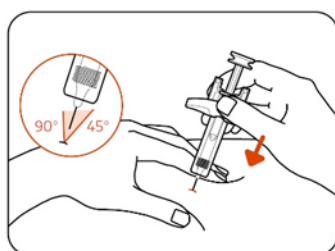


Figure G

d: Release the pinched skin

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

- **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 trauma to the tissue. If this happens, safely throw away the syringe in a sharps container, and get a new syringe to give the injection.

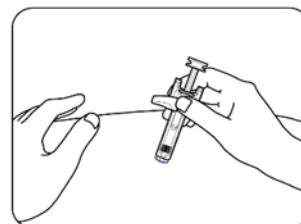


Figure H

e: Inject the medicine

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

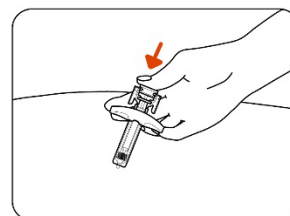


Figure I

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 J).

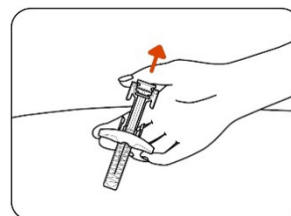


Figure J

g: Examine the injection site

Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds (Figure K). **Do not** rub the injection site. You may have slight bleeding, this is normal. Apply an adhesive bandage if needed (Figure L).

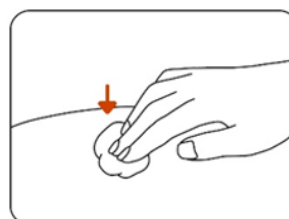


Figure K

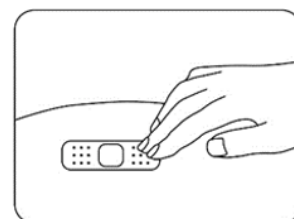


Figure L

Step 4: Throw away (dispose of) the used Zilbrysq syringe

Throw away the used syringe into a sharps container (Figure M) right away.

Do not throw away the syringe in your household trash.

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

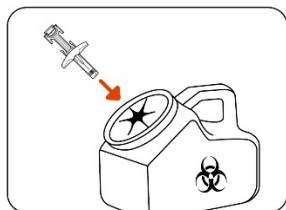


Figure M

If you forget to use Zilbrysq

If you miss your dose, administer the dose as soon as possible on the same day and then resume dosing at the scheduled time on the following day.

Do not administer more than one dose per day.

Do not take a double dose to make up for the dose you missed.

If you use too much Zilbrysq

If you think that you have used too much Zilbrysq, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Zilbrysq?

Remind any doctor, dentist or pharmacist you visit that you are using Zilbrysq.

Call your doctor straight away if you:

Experience any of the following meningococcal infection symptoms:

- Headache with additional symptoms such as nausea, 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.

Things you should not do

Do not use:

- if the expiration date on the packaging has passed
- if the carton seals have been broken
- if the pre-filled syringe has been dropped or looks damaged
- if the liquid has ever been frozen (even if thawed)
- if the medicine is cloudy, discolored, or contains floating particles
- if the needle cap is cracked or broken, missing or not securely attached to the syringe
- if the needle is bent, broken, or missing
- if the dose on the label does not correspond to your prescription.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Zilbrysq affects you.

Zilbrysq is not likely to affect your driving and use of machines.

Looking after your medicine

- Store in a refrigerator between 2°C – 8°C.
- Do not freeze.
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- The Zilbrysq pre-filled syringe may be stored at room temperature (up to 30°C) for a single period of a maximum 3 months with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 3 months or by the expiry date, whichever occurs first. A field for the date is provided on the carton to record the date removed from the refrigerator.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Discard after the expiry date, or 3 months after being removed from the refrigerator.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site reactions: <ul style="list-style-type: none">Such as bruising, pain or rash Infection: <ul style="list-style-type: none">Upper respiratory tract infections such as sore throat, blocked nose and headache. Gastrointestinal disorders: <ul style="list-style-type: none">Diarrhoea Skin disorders: <ul style="list-style-type: none">Morphoea (condition that causes localised discoloured and hardened areas of the skin).	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction: <ul style="list-style-type: none">Difficulty breathing or swallowingLow blood pressure, which can make you dizzy or light-headedSwelling of the face, lips, tongue or throatSevere itching of the skin, with a red rash or raised bumps. Meningococcal Infection: <ul style="list-style-type: none">Headache with additional symptoms such as nausea, vomiting, fever and stiff neck or backFever with or without a rashEyes sensitive to lightConfusion / drowsinessMuscle pain with flu-like symptoms. Serious Infection: <ul style="list-style-type: none">Fever, fast heart rate, fast breathing, confusion, and body pain Pancreatitis <ul style="list-style-type: none">Sudden severe abdominal pain, nausea, vomiting, fevers, sweating, rapid pulse.	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Zilbrysq contains

Active ingredient (main ingredient)	Zilucoplan tetrasodium
Other ingredients (inactive ingredients)	Monobasic sodium phosphate monohydrate, dibasic sodium phosphate, sodium chloride and water for injections

Do not take this medicine if you are allergic to any of these ingredients.

Pre-filled syringe components are not made with natural rubber latex.

What Zilbrysq looks like

Zilbrysq is clear to slightly opalescent and colorless, free of visible particles. It comes in a single use disposable pre-filled syringe.

Zilbrysq is available in unit packs containing 7 pre-filled syringes or multipacks containing 28 (4 packs of 7) pre-filled syringes in the following strengths:

- A pre-filled syringe of 0.416 mL containing 16.6 mg of zilucoplan (as zilucoplan tetrasodium) (AUST R 410994)
- A pre-filled syringe of 0.574 mL containing 23.0 mg of zilucoplan (as zilucoplan tetrasodium) (AUST R 414648)
- A pre-filled syringe of 0.810 mL containing 32.4 mg of zilucoplan (as zilucoplan tetrasodium) (AUST R 414649)

Who distributes Zilbrysq

UCB Pharma

A division of UCB Australia Pty Ltd

Phone: +613 9828 1800

Website: www.ucbpharma.com.au

E-mail: ucbcares.au@ucb.com

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