

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.

1. Why am I using Zarzio?

Zarzio contains the active ingredient filgrastim. Zarzio is used to encourage your bone marrow to produce more neutrophils, a type of white blood cell. You may have been prescribed Zarzio because you are receiving treatment for cancer, are receiving a bone marrow or stem cell transplant, are donating stem cells for another person, are suffering from severe chronic neutropenia or are receiving medicines for HIV infection. For more information, see Section [1. Why am I using Zarzio?](#) in the full CMI.

2. What should I know before I use Zarzio?

Do not use if you have ever had an allergic reaction to Zarzio or any of the ingredients listed at the end of the CMI, or to any medicines or products that are produced using the bacteria E.coli.

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 Zarzio?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zarzio 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 Zarzio?

Zarzio is injected under the skin (subcutaneous). More instructions can be found in Section [4. How do I use Zarzio?](#) in the full CMI.

5. What should I know while using Zarzio?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist you visit that you are using Zarzio.• Keep all of your doctor's appointments so that your health can be monitored.• Tell your doctor straight away if you become pregnant.• Go straight to your hospital if you notice any signs or symptoms of infection.
Things you should not do	<ul style="list-style-type: none">• Do not use Zarzio to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or using any machines or tools until you know how Zarzio affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep Zarzio in a refrigerator at a temperature of 2°C to 8°C.• Keep your medicine in its pack until it is time to use it. Protect it from light.

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

6. Are there any side effects?

Common side effects include bone, back, muscle, joint, mouth or throat pain; swelling or stiffness of joints; muscle spasms; abdominal discomfort; diarrhoea; constipation; nausea; vomiting; severe nose bleeds; reddish or purplish bumps or blotches, mouth ulcers; numbness; tingling in the hands and feet; injection site reactions; cough; hair loss; headache; looking pale; loss of appetite; unusual weakness; difficulty sleeping. Serious side effects include rash, itching or hives; shortness of breath, wheezing, difficulty, or rapid breathing; tiredness, fever; easy bruising or bleeding; coughing up blood; swelling; faintness; rapid pulse or sweating; painful skin lesions; chest pain; left shoulder pain; pain in the upper left side of the stomach; swelling of your stomach-area; reduced urination; blood in the urine. 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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Zarzio. **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 Zarzio.**

Where to find information in this leaflet:

- [1. Why am I using Zarzio?](#)
- [2. What should I know before I use Zarzio?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Zarzio?](#)
- [5. What should I know while using Zarzio?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Zarzio?

Zarzio contains the active ingredient filgrastim. Zarzio belongs to a group of medicines called cytokines and is a copy of a substance normally present in your body, called Granulocyte Colony Stimulating Factor or G-CSF. Using gene technology, Zarzio is produced in a specific type of bacteria, called *E. coli*. G-CSF is produced in the bone marrow and assists in the production of neutrophils, which are a type of white blood cell. Neutrophils help the body fight infections by surrounding and destroying the bacteria that cause them. G-CSF also helps neutrophils to do this work better. Zarzio works by encouraging the bone marrow to produce more neutrophils.

Zarzio can be used:

- to increase the number of white blood cells after treatment with chemotherapy to help prevent infections;
- to increase the number of white blood cells after a bone marrow transplant to help prevent infections;
- before high-dose chemotherapy to make the bone marrow produce more stem cells which can be collected and given back to you after your treatment. These can be taken from you or from a donor. The stem cells will then go back into the bone marrow and produce blood cells;
- to increase the number of white blood cells if you suffer from severe chronic neutropenia to help prevent infections;
- in patients with advanced HIV infection which will help reduce the risk of infections

2. What should I know before I use Zarzio?

Warnings

Do not use Zarzio if:

- you are allergic to filgrastim, any of the ingredients listed at the end of this leaflet or any medicines or products are produced using the bacteria *E.coli*. Always check the ingredients to make sure you can use this medicine.
- at the same time as your chemotherapy or radiotherapy.
- in the 24 hours before or after you receive your chemotherapy, radiotherapy, bone marrow transplant or stem cell transplant.
This is because these types of treatments may stop Zarzio from increasing the number of infection-fighting neutrophils.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes
- have any other medical conditions
 - a medical condition affecting the bone marrow or blood
 - family history of a genetic disorder
 - sickle cell disease
 - problems with your kidneys, liver, heart or other organs
 - previous treatment for cancer
 - any infections, cancers or tumours.
- take any medicines for any other condition
- are not sure whether you should use Zarzio.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if the active ingredient in Zarzio passes into the milk.

Use in Children

- There is limited experience with the use of Zarzio in children. Your doctor will discuss the risks and benefits of using it in children.

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.

Some medicines may interfere with Zarzio and affect how it works.

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

4. How do I use Zarzio?

How much to inject

- Your doctor will tell you how much Zarzio to use. How much you will need to use will depend on the reason for your treatment, your body weight and the number of neutrophils in your blood.
- For Zarzio to work properly, you have to use it exactly as your doctor has instructed.
- Follow the instructions provided and use Zarzio until your doctor tells you to stop.

When to use Zarzio

- Zarzio should be used at the same time each day.
- Your doctor will tell you when to begin your treatment and when to stop.
- Your doctor will tell you how many injections you need each week and on which days they should be given.
 - Patients receiving chemotherapy or who have received a bone marrow or stem cell transplant are only required to use Zarzio for short periods of time until the number of infection-fighting neutrophils are restored (usually 1 to 3 weeks).
 - Stem cell donors should receive Zarzio treatment for 4 to 5 days.
 - Patients with severe chronic neutropenia are required to use Zarzio regularly and for a long period of time, to keep the number of infection-fighting neutrophils at a normal level.
 - Patients with HIV infection need to use Zarzio daily until their neutrophil numbers are normal. Usually, the dose is then reduced to three injections per week to maintain the neutrophil numbers.

How to use Zarzio

- Zarzio is given by injection. This can be either:
 - into the tissues just below the skin, called a subcutaneous injection, or
 - into the vein, called an intravenous injection
- Intravenous injections will be given by a doctor or nurse.
- For subcutaneous injections, in some instances, your doctor, nurse or pharmacist may suggest that you or

your carer be taught how to administer the injection. This will allow you to have your Zarzio injection at home.

- **Follow all directions given to you by your doctor, nurse or pharmacist carefully.** They may differ from the information contained in this leaflet.
- **If you do not understand the instructions, ask your doctor, nurse or pharmacist for help.**

Where to inject Zarzio

The best injection sites are:

- **your abdomen, except for the area around the navel (belly button) or**
- **the front side of your thighs.**

The sites are shown in the pictures below.



- **Change the injection site each time you inject to avoid soreness at any one site.**

Things to do before you inject

Make sure you have all materials you need for your injection:

- a new Zarzio syringe
- an alcohol swab
- a puncture-resistant sharps container.

Follow these instructions exactly to help avoid contamination and possible infection.

If you are unsure, check with your doctor, nurse or pharmacist.

1. Find a clean, flat working surface, such as a table, where you can inject undisturbed.
2. Remove the syringe from the refrigerator. For a more comfortable injection, leave at room temperature for approximately 30 minutes. Do not warm Zarzio in any other way (e.g. do not warm in a microwave or hot water).
3. Check that the syringe has NOT been used before.
4. Do not shake the syringe. If the Zarzio solution appears frothy or bubbly, allow the syringe to sit undisturbed for a few minutes to reduce the froth or bubbles before measuring your dose.

- Do not remove the needle cover until you are ready to inject.
- Check the expiry date on the label. Do not use if the date has passed the last day of the month shown.
- Check the appearance of the solution. The solution should be clear and colourless or slightly yellow in colour. If it is cloudy, coloured or there are clumps or flakes, you must not use it.
- Wash and dry your hands thoroughly.

How to prepare for your injection

- Hold the syringe vertically with the needle pointing up, this helps reduce the amount of medicine that may leak out of the needle. Carefully remove the needle cover, taking care not to touch the exposed needle.
- Check the dose (in mL) that your doctor has prescribed and locate the correct volume mark on the syringe barrel. Carefully push the plunger until the grey upper edge of the plunger reaches the correct volume mark. This will push the air and any excess liquid out of the syringe.
- Double-check that you have the correct dose.**

How to inject

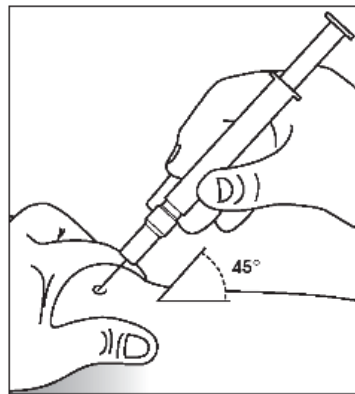
This section contains information on how to give yourself an injection of Zarzio. **It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse.** Zarzio is provided with or without a needle safety guard and you will be shown how to use this by your doctor or nurse. If you are not sure about giving the injection or you have any questions, please ask your doctor or nurse for help.

Caution: Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap.

- Wash your hands
- Remove one syringe from the pack and remove the protective cap from the injection needle. Syringes are embossed with graduation rings in order to enable partial use if required. Each graduation ring corresponds to a volume of 0.1 mL. If partial use of a syringe is required, remove unwanted solution before injection.
- Clean the skin at the injection site using an alcohol wipe.
- Form a skin fold by pinching the skin between thumb and forefinger.
- Insert the needle into the skin fold with a quick, firm action. Inject the Zarzio solution as you have been shown by your doctor. You should check with your doctor or pharmacist if you are not sure.

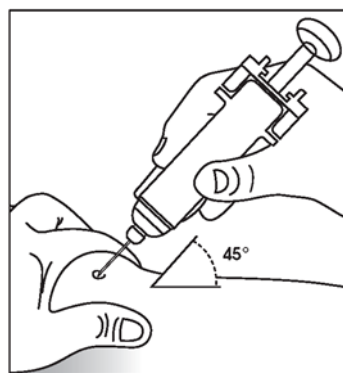
Pre-filled syringe without needle safety guard

- Always keeping your skin pinched, depress the plunger slowly and evenly.
- After injecting the liquid, remove the needle and let go of your skin.
- Put the used syringe in the disposal container. Use each syringe only for one injection.



Pre-filled syringe with needle safety guard

- Always keeping your skin pinched, depress the plunger slowly and evenly until the entire dose has been given and the plunger cannot be depressed any further. Do not release the pressure on the plunger!
- After injecting the liquid, remove the needle while maintaining pressure on the plunger and then let go of your skin.
- Let go of the plunger. The needle safety guard will rapidly move to cover the needle.
- Discard any unused product or waste material. Only use each syringe for one injection



Do not change the dose or the way you inject Zarzio without consulting your doctor. Always follow your doctor's instructions.

If you forget to use Zarzio

If you miss your scheduled dose, inject it as soon as you can - provided that it is still on the same day.

If you miss a whole day before you remember to inject yourself, do not take a 'catch-up' dose or increase your next dose.

Talk to your doctor, nurse or pharmacist as soon as possible about the missed dose.

If you use too much Zarzio

If you think that you have used too much Zarzio, 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 Zarzio?

Things you should do

- Remind any doctor, dentist, pharmacist or nurse you visit that you are using Zarzio.
- Keep all of your doctor's appointments so that your health can be monitored. Your doctor may order blood tests to check the levels of infection-fighting neutrophils and other blood cells. Treatment with Zarzio leads to changes in the numbers of certain blood cells. Blood tests may also be undertaken after you have completed your Zarzio treatment until your blood cells have returned to normal levels.

Call your doctor straight away if you:

- become pregnant

Go straight to your hospital if you:

- Notice any signs or symptoms of infection. There are many ways an infection may show itself. Symptoms of an infection include: fever (a temperature of 38.2°C or greater, or as your doctor suggests), chills, rash, sore throat, diarrhoea, earache, difficult or painful breathing, coughing or wheezing.

Things you should not do

- Do not use Zarzio to treat any other complaints unless your doctor tells you to.
- Do not give Zarzio to anyone else, even if they have the same condition as you.

Driving or using machines

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

The effects on your ability to drive or use machines whilst taking Zarzio are not known.

Looking after your medicine

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

- **Keep Zarzio in a refrigerator at a temperature of 2°C to 8°C.**

- Exposure to room temperature for up to 8 days will not harm Zarzio.
- **Keep Zarzio in its carton until it is time to use it. Protect it from light.**
- **Keep it where children cannot reach it.**

When to discard your medicine

Once you have injected Zarzio, **do not put the cover back on the used syringe.**

Discard the used syringe into an approved, puncture-resistant, sharps container and keep it out of the reach of children.

Never put used syringes into your normal household rubbish bin.

Dispose of the full puncture resistant sharps container as instructed by your doctor, nurse or pharmacist.

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
<p>Muscle and Skeleton:</p> <ul style="list-style-type: none">• temporary bone pain, such as in the lower back or in the long bones of the arms or legs. <p>This pain is usually relieved with non-prescription painkillers, like paracetamol. If you continue to have bone pain even after having taken this form of pain relief, you should speak to your doctor, as you may need a prescription medicine.</p> <ul style="list-style-type: none">• back pain• pain, swelling, warmth or stiffness of joints• worsening of existing arthritis• muscle pain• muscle spasms <p>Gut and Digestion:</p> <ul style="list-style-type: none">• abdominal discomfort• diarrhoea or constipation	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> nausea (feeling sick) and/or vomiting <p>Blood:</p> <ul style="list-style-type: none"> pink, red or blue/purple spots or bumps on the skin bleeding or bruising more than usual, severe nose bleeds reddish or purplish blotches under the skin <p>Eyes, ears and mouth:</p> <ul style="list-style-type: none"> sore throat sore mouth, mouth ulcers <p>Nervous System:</p> <ul style="list-style-type: none"> numbness tingling in the hands and feet <p>Skin:</p> <ul style="list-style-type: none"> redness, swelling or itching at the site of injection skin disorders - worsening of existing symptoms skin rash or red, itchy spots swelling of hands, legs, ankles, feet or any other part of the body <p>General:</p> <ul style="list-style-type: none"> cough hair loss headache looking pale loss of appetite unusual weakness difficulty sleeping 	
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Serious side effects

Serious side effects	What to do
<p>General:</p> <ul style="list-style-type: none"> chest pain fever general feeling of tiredness left shoulder tip pain frequent infections tiredness, fever and easy bruising or bleeding. dizziness or feeling light headed faintness rapid pulse or sweating <p>Lungs and upper airways:</p> <ul style="list-style-type: none"> coughing up blood, bleeding from the lung breathing problems such as shortness of breath, rapid breathing 	<p>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.</p>

<p>Gut, Digestion and Urine-related:</p> <ul style="list-style-type: none"> pain in the upper left side of the stomach (abdomen) swelling of your stomach-area (abdomen) and feeling of fullness less frequent urination blood in the urine <p>Skin</p> <ul style="list-style-type: none"> fever and painful skin lesions, most commonly on your arms, legs and sometimes on your face and neck swelling or puffiness <p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> rash over a large area of the body, itching or hives shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body 	
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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 Zarzio contains

Active ingredient (main ingredient)	filgrastim (rbe)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> glutamic acid sorbitol polysorbate 80 sodium hydroxide (for pH adjustment) water for injections.
Potential allergens	The needle cover on the pre-filled syringe contains a derivative of latex.

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

What Zarzio looks like

Zarzio® is a colorless, to slightly yellowish solution and supplied as a ready to use syringe.

Available in the following strengths:

- 300 micrograms of filgrastim in a volume of 0.5 mL (AUST R 195066);
- 480 micrograms of filgrastim in a volume of 0.5 mL (AUST R 195065).

The syringes are packed in pack sizes of 1, 5 and 10.

Not all strengths or presentations may be marketed.

Who distributes Zarzio

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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