

Zarzio®

filgrastim 300 µg/0.5 mL and 480 µg/0.5 mL solution for injection (pre-filled syringes)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Zarzio®.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ZARZIO® IS USED FOR

Zarzio® 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.

Your doctor has prescribed Zarzio® because:

1. You are receiving chemotherapy for cancer.

Unfortunately, some chemotherapy will reduce the number of neutrophils in your body. Although Zarzio® is not a treatment for cancer, it does help the body to make new neutrophils. This will reduce the chance of developing infections that might require antibiotics and/or hospital stays. It may even increase your chance of receiving your chemotherapy on time and at the right dose.

2. You are receiving a bone marrow or stem cell transplant

Blood cells are produced in the bone marrow and arise from special 'parent cells', called stem cells. Some chemotherapy has toxic effects on bone marrow, so your doctor may choose to collect stem cells from your bone marrow or blood, or from a donor's bone marrow or blood, before you receive your chemotherapy. These collected stem cells are then stored and may be given back to you later, to replace those lost during chemotherapy. This procedure is called a bone marrow or stem cell transplant.

There are normally only a small number of stem cells in your blood; Zarzio® is typically used to increase this number before stem cell collection. You may also receive Zarzio® after a bone marrow or stem cell transplant, to help speed up your recovery.

3. You are donating stem cells for another person

If you are aged between 16 and 60 years and have volunteered to donate your stem cells for another person, Zarzio® may be used to increase the number of stem cells in your blood before they are collected. Your stem cells can then be given to a patient after he/she has received their chemotherapy.

4. You are suffering from severe chronic neutropenia

Severe chronic neutropenia is a disease in which the body does not make enough neutrophils, increasing your risk of fever and/or infection. Zarzio® helps the body to make and maintain the right number of infection-fighting neutrophils. This decreases the risk of infection and the need for antibiotics and/or hospital stays.

5. You are receiving medicines for HIV infection

Some medicines used to treat HIV (Human Immunodeficiency Virus) infection, or its complications, can reduce the number of infection-fighting neutrophils in your blood. Your doctor may prescribe Zarzio® if the number of neutrophils falls too low.

By boosting your neutrophil count, Zarzio® will improve your body's ability to fight infection and may increase your chance of receiving the full dose of some of your HIV medicines. Zarzio® is not a treatment for HIV infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

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

BEFORE YOU START TO USE ZARZIO®

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicines containing Filgrastim.
- any of the other ingredient(s) listed at the end of this leaflet.
- any other similar medicines or products that are produced using the bacteria E.Coli.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use Zarzio® at the same time as your chemotherapy or radiotherapy.

Do not use Zarzio® in the 24 hours before or the 24 hours 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.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use Zarzio® if it has been left out of the refrigerator for more than three days.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding or plan to breast-feed.

Tell your doctor if you have or have had any of the following medical conditions:

- a medical condition affecting the bone marrow or blood
- a family history of genetic disorder
- sickle cell disease
- problems with your kidneys, liver, heart or other organs
- previous treatment for cancer
- any infections, cancers or tumours.

If you have not told your doctor about any of the above, tell him/her before you start using Zarzio®.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, particularly those that may affect the blood. Also tell them about any medicines you buy without a prescription from your pharmacy, supermarket or health food shop.

HOW TO USE ZARZIO®

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 or pharmacist for help.

Zarzio® is given by injection, usually into the tissue just below the skin. This is called a subcutaneous injection and it is a simple procedure.

Your doctor, nurse or pharmacist may suggest that you or your carer be taught how to give a subcutaneous injection. This will allow you to have your Zarzio® injection at home.

Zarzio® is sometimes given by injection into a vein. This is called intravenous injection and is generally given by a doctor or a nurse.

How much to inject

For Zarzio® to work properly, you have to use it exactly as your doctor has instructed.

Your doctor will tell you the strength of Zarzio® you need and how much you require. How much you need will depend on the reason for your treatment, your body weight and the number of neutrophils in your blood.

Where to inject

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.

When to inject

For best results, you should inject Zarzio® at about the same time each day.

Your doctor will tell you when to begin your treatment and when to stop it.

How long to use it

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 a 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 neutrophils numbers are normal. Usually, the dose is then reduced to three injections per

week to maintain the neutrophil numbers.

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.
5. Do not remove the needle cover until you are ready to inject.
6. Check the expiry date on the label. Do not use if the date has passed the last day of the month shown.
7. 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.
8. Wash and dry your hands thoroughly.

How to prepare for your injection

1. 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.
2. 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

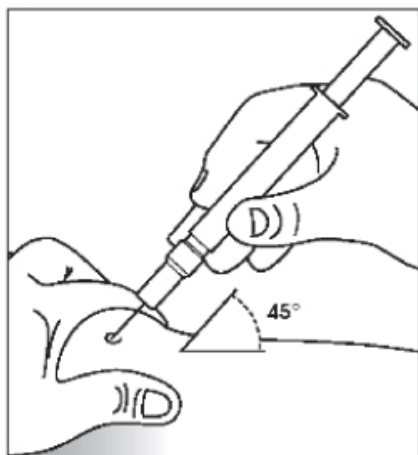
This section contains information on how to give yourself an injection of Zarzio. It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. Zarzio is provided with or without a needle safety guard and you will be shown how 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.

1. Wash your hands
2. 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.
3. Clean the skin at the injection site using an alcohol wipe.
4. Form a skin fold by pinching the skin between thumb and forefinger.

5. 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.

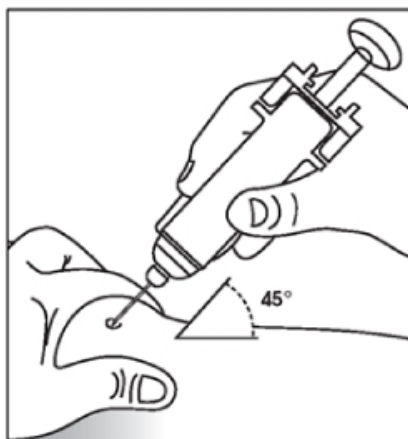
Pre-filled syringe without needle safety guard

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



Pre-filled syringe with needle safety guard

6. 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!
7. After injecting the liquid, remove the needle while maintaining pressure on the plunger and then let go of your skin.
8. Let go of the plunger. The needle safety guard will rapidly move to cover the needle.
9. 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 your injection

If you miss your scheduled dose, inject it as soon as you can, provided 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 inject too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Zarzio®. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Too much Zarzio® may lead to neutrophil levels that are too high. Research has shown that doses almost 15 times greater than the most common dose do not immediately result in any harmful effects.

WHILE YOU ARE TAKING ZARZIO®

Things you must do

Be alert for any signs or symptoms of infection.

There are many ways an infection can show itself.

You should watch for:

- 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.

If you develop any of these symptoms, go straight to the hospital.

If you are about to start on any new medication, tell your doctor, nurse or pharmacist that you are using Zarzio®.

Tell any other doctors who treat you that you are using this medicine.

If you become pregnant during treatment with Zarzio®, tell your doctor immediately.

Keep all your doctor's appointments so that your health can be monitored.

Treatment with Zarzio® leads to changes in the number of certain blood cells. Your doctor may order blood tests to check the levels of infection-fighting neutrophils and blood cells.

Blood tests may also be undertaken after you have completed your Zarzio® treatment until your blood cells have returned to normal levels.

Things you must 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.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you have any problems while using Zarzio®, even if you do not think the problems are connected with the medicine or not listed in this leaflet.

All medicines can have side effects. Some side effects may be serious and need medical attention. Other side effects are minor and are likely to be temporary. You may experience side effects caused by other medicines you are taking at the same time as Zarzio®.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you.

Some of these are known side effects of chemotherapy and may not be related to Zarzio®:

- temporary bone pain, such as in the lower back or in the long bones of the arms and legs. 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 medication
- abdominal discomfort
- bleeding or bruising more than usual, severe nose bleeds
- reddish or purple blotches under the skin
- cough, breathlessness
- diarrhoea
- hair loss

- headache
- painful and swollen joints
- worsening of existing arthritis
- muscle pain
- redness, swelling or itching at the site of injection
- skin disorders - worsening of existing symptoms
- skin rash or red, itchy spots
- sore mouth, mouth ulcers
- tiredness, looking pale.

Tell your doctor immediately if you notice any of the following:

- pain in the upper left side of the stomach (abdomen)
- left shoulder pain
- dizziness
- fever and painful skin lesions, often painful, most commonly on your arms, legs and sometimes on your face and neck
- blood in the urine
- tiredness, fever and easy bruising or bleeding

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- breathing problems such as shortness of breath, rapid breathing
- fever
- swelling or puffiness
- less frequent urination
- swelling of your stomach-area (abdomen) and feeling of fullness
- general feeling of tiredness.

These may be serious side effects of Zarzio®. You may need urgent medical attention.

Serious side effects are rare or uncommon.

If any of the following happen, stop taking Zarzio® and go straight to the hospital, as you may need urgent medical attention:

- rash over a large area of the body, itching or hives
- shortness of breath, wheezing or difficulty breathing
- coughing up blood, bleeding from the lung
- swelling of the face, lips, tongue or other parts of the body
- faintness
- rapid pulse or sweating.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Zarzio®. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people.

AFTER USING ZARZIO®

Storage

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

Exposure to room temperature for up to 3 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.

Disposal

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.

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

Never put used syringes into your normal household rubbish bin.

PRODUCT DESCRIPTION

What it 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;
- 480 micrograms of filgrastim in a volume of 0.5 mL

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

Not all strengths or presentations may be marketed.

Ingredients

The active ingredients in Zarzio®:

- Filgrastim.

Inactive ingredients:

- glutamic acid
- sorbitol
- polysorbate 80
- sodium hydroxide (for pH adjustment)
- water for injections.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW
2113
Australia
Tel: 1800 726 369

This leaflet was prepared September 2021.

Australian Register Number(s)

Zarzio® 300 µg/0.5 mL AUST R
195066 (syringe)

Zarzio® 480 µg/0.5 mL AUST R
195065 (syringe)