

ZARZIO[®]

filgrastim (rbe) 300 µg/0.5 mL and 480 µg/0.5 mL solution for injection in 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, nurse 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, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Zarzio is used for

Zarzio solution for injection contains the active ingredient, filgrastim.

Filgrastim is a copy of a substance normally present in your body, called Granulocyte Colony Stimulating Factor or G-CSF. Through the use of 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 be more effective. Filgrastim does not cure the underlying illness but it is an important supportive therapy.

Your doctor may have prescribed Zarzio because:

- **you are receiving chemotherapy for cancer.** 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, and this will reduce your chance of developing infections that might require treatment with antibiotics and/or hospital stays. Zarzio may also help to keep your chemotherapy treatment on schedule.
- **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 before you receive your chemotherapy or from a donor's bone marrow or blood. These collected stem cells are then stored and may be given to you later to replace those lost during chemotherapy.
- 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.
- **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 the person after he/she has received their chemotherapy.

- **you are suffering from severe chronic neutropenia.** Severe chronic neutropenia is a condition 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, decreasing the risk of infection and the need for antibiotics and/or hospital stays.
- **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.

Your doctor may have prescribed it for another purpose.

Zarzio is not addictive.

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

Before you use Zarzio

When you must not use it

Do not use Zarzio if:

1. you have an allergic reaction to Zarzio or any ingredients listed at the end of this leaflet
2. you have severe congenital neutropenia (Kostmann's syndrome) - and inherited lack of neutrophils
3. the package is torn or shows signs of tampering
4. the expiry date printed on the pack has passed
If you take this medicine after the expiry date has passed, it may not work as well.
5. any other medicines or other products that are produced by DNA technology 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 this medicine at the same time as your chemotherapy or radiotherapy.

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

If you are not sure if you should be using Zarzio, talk to your doctor.

Before you start to use it

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

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

- some cancers, including myelodysplastic syndrome and some leukaemias
- past problems with your spleen eg: splenomegaly (enlarged spleen)
- sickle cell disease (an inherited disease in which red blood cells are sickle shaped)
- osteoporosis (thinning of the bones) or other bone diseases
- rheumatoid arthritis
- radiotherapy or chemotherapy as a treatment for cancer
- cancer where the tumour has got in to your bone marrow
- an infection in your bone marrow
- blood clotting problems and you are going to donate stem cells for another person
- HFI (hereditary fructose intolerance) – Zarzio contains sorbitol which may affect this condition

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known whether Zarzio is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Zarzio when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

Tell your doctor if you are breast-feeding or plan to breastfeed.

It is not known whether Zarzio passes into breast milk. Breast-feeding is not recommended while you are taking Zarzio.

Tell your doctor if you are taking any blood thinning medications.

Tell your doctor if you are below 16 or over 60 years, if you are being prepared to be a stem cell donor.

Zarzio contains sorbitol.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before using it.

If you have not told your doctor about any of the above, tell him/her before you start using Zarzio. Your doctor will decide whether it is safe for you to use Zarzio.

There is limited experience with the use of Zarzio in children.

Your doctor will discuss the risks and benefits of using this medicine in children.

Taking other medicines

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

Some medicines and Zarzio may interfere with each other. These include:

- lithium (e.g. Lithicarb[®], Priadel[®])
- some chemotherapy medicines such as fluororacil.

These medicines may be affected by Zarzio or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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.

Zarzio is given by injection, usually into the tissues 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 injection at home.

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

If you do not understand the instructions, ask your doctor, nurse or pharmacist for help.

How much to inject

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

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to inject.

Follow the instructions they give you.

Where to inject Zarzio

The best injection sites are the abdomen (except for the area around the belly button) and the front or side of the thighs (see picture below). Change the injection site each time you inject to avoid soreness at any one site.



When to inject Zarzio

Inject Zarzio at about the same time each day.

Injecting Zarzio at the same time each day will have the best effect. It will also help you remember when to have it. Your doctor will tell you when to begin your treatment and when to stop.

How long to use Zarzio

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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

neutrophil numbers. Your doctor will tell you how many injections you need each week and on which days they should be given.

Things to do before you inject

Make sure that you have all the materials you need for the injection:

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

Before you inject Zarzio, always check the following:

- that the Zarzio syringe has not been used before
- the expiry date on the syringe. Do not use if the date has passed the last day of the month shown
- that the solution is not cloudy or discoloured and contains no clumps or flakes. Only clear solutions without particles should be used.

Follow these instructions exactly to help avoid contamination and possible infection. If unsure, check with your doctor, nurse or pharmacist.

1. Remove the Zarzio syringe from the refrigerator 20 to 30 minutes before the injection is due and allow it to reach room temperature. Do not warm Zarzio in any way (do not warm it in a microwave or in hot water). Use each syringe once only. Do not shake. If the 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.
2. Wash and dry your hands thoroughly. Find a clean, flat working surface, such as a table where you can inject undisturbed. Set up the equipment you will need (as stated above).

- While keeping the needle shield on, grasp the needle cap and remove it carefully. Do not remove the needle cover until you are ready to inject.
- Hold the syringe vertically with the needle pointing up. This helps to reduce the amount of medicine that may leak out of the 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 you have the correct dose.

How to inject Zarzio

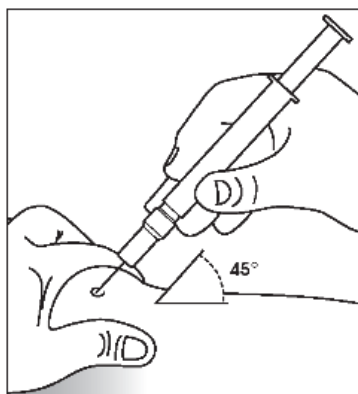
This section contains information on how to give yourself an injection of Zarzio. **It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse.** Zarzio is provided with or without a needle safety guard and you will be shown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

- 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.

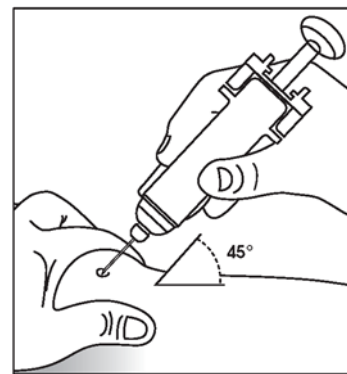
Pre-filled syringe without needle safety guard

- 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, nurse or pharmacist. Always follow your doctor's instructions.

If you forget your injection

Take your dose as soon as you remember, provided it is on the same day, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Advise your doctor, nurse or pharmacist as soon as possible about the missed dose.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor, nurse or pharmacist.

If you have trouble remembering to have your injection, ask your pharmacist for some hints.

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 using Zarzio

Things you must do

Be alert for any signs or symptoms of infection.

There are many ways an infection may 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
- ear ache
- difficult or painful breathing, coughing or wheezing.

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

If you are about to be started on any new medicine, remind your doctor, nurse and pharmacist that you are taking Zarzio.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests and/or x-rays, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

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

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 take Zarzio to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Things to be careful of

Be careful driving or operating machinery until you know how Zarzio affects you.

However, it is not expected that Zarzio will affect your ability to drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zarzio.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor as soon as possible if you have any problems while

using Zarzio, even if you do not think the problems are associated with the medicine or are not listed in this leaflet.

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

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

Tell your doctor 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:

- bone pain, such as in the lower back or in the long bones of arms or legs. This pain is usually relieved with non-prescription pain killers, 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, nose bleeds
- reddish or purplish blotches under the skin
- pain or difficulty passing urine
- cough, breathlessness
- diarrhoea or constipation
- loss of appetite
- hair loss
- headache
- nausea (feeling sick) and/or vomiting
- pain, swelling, warmth or stiffness of joints
- worsening of existing arthritis
- muscle pain
- redness, swelling or itching at the injection site
- skin disorders – worsening of existing symptoms
- skin rash or red itchy or sore spots

- sore mouth or throat, including mouth ulcers
- tiredness, weakness and pale looking
- swelling of hands, legs, ankles, feet or any other part of the body
- swelling or puffiness
- trouble sleeping

If any of the following happen, tell your doctor immediately:

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

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- coughing up blood, bleeding from the lung
- chest pain
- breathlessness or difficulty breathing
- fever
- frequent infections
- rapid pulse or sweating

The above list includes very serious side effects. 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 your medicine in the original container, protected from light.

If you take it out of its original container it may not keep well.

Keep your medicine in the refrigerator where the temperature stays between 2°C and 8°C. Do not freeze.

Keep it where children cannot reach it.

Disposal

Once you have injected Zarzio, do not put the cover back on the used syringe. Place the used syringe into an approved, puncture-resistant, sharps container.

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.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Zarzio is a colourless, to slightly yellowish solution and supplied as a solution for injection in two types of pre-filled syringes:

Zarzio 300 micrograms/0.5mL pre-filled syringe – glass syringe with an injection needle contained within a sterile blister pack.

Zarzio 480 micrograms/0.5mL pre-filled syringe – glass syringe with an injection needle contained within a sterile blister pack.

Available in packs of 1, 3, 5 or 10 pre-filled syringes.

Not all strengths and presentations are marketed.

Ingredients

Active ingredients:

- Zarzio 300 micrograms/0.5mL pre-filled syringe – 300 micrograms (30MU) of filgrastim (rbe)
- Zarzio 480 micrograms/0.5mL pre-filled syringe – 480 micrograms (48MU) of filgrastim (rbe)

Inactive ingredients:

- glutamic acid
- polysorbate 80
- water for injections
- sorbitol (E420)
- sodium hydroxide for pH adjustment.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Zarzio is supplied by:

Australia

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park NSW 2113

Australia

Tel: 1800 726 369

New Zealand

Novartis New Zealand Ltd

PO Box 99102

Newmarket

Auckland 1149

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