

ZARZIO[®] SOLUTION FOR INJECTION OR INFUSION

Filgrastim (30MU/0.5ml)

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What ZARZIO[®] is used for

ZARZIO[®] is used mainly for reducing the duration of neutropenia and to prevent the occurrence of neutropenia associated with fever for those who undergo treatment with medicines for cancer. Neutropenia means reduction in neutrophils (type of white blood cell important in the body's fight against infection). It is also used for reducing the duration of neutropenia in patients undergoing myeloablative therapy (therapy aimed at reducing the bone marrow cells) which is followed by bone marrow cell transplantation.

It is used for mobilization of blood progenitor cells (progenitor cells are nothing but the cells that can differentiate into a specific type of cells).

It is also used for reducing the duration of neutropenia in patients (children or adults), with neutropenia less than or equal to the count of $0.5 \times 10^9/L$ who present this condition by birth and those who have severe infections. It is also used in patients with persistent neutropenia whose count is less than or equal to $1.0 \times 10^9/L$ like in patients with HIV infection.

How ZARZIO[®] works

ZARZIO[®] is a man-made form of granulocyte colony-stimulating factor

(G-CSF). Human G-CSF is a substance produced by our body which regulates the production and release of neutrophils from the bone marrow.

ZARZIO[®] stimulates the growth of neutrophils along with a minor increase in other type of blood cells like monocytes, eosinophils and basophils

Before you use ZARZIO[®]

- When you must not use it

Do not take ZARZIO[®] if you are allergic to filgrastim or any of the other ingredients in ZARZIO[®].

Pregnancy and lactation

Filgrastim is not recommended during pregnancy as there are no adequate data available regarding its use in pregnant woman.

It is not known if ZARZIO[®] passes into your breast milk. Your doctor will decide whether to discontinue breast-feeding or to discontinue ZARZIO[®] therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for you. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before taking ZARZIO[®], tell your doctor if you:

- have a condition called congenital neutropenia or have any evidence of leukemia (blood cancer)
- have any disorder associated with the production of blood cells (myelodysplastic syndrome)
- have sickle cell disease which is a group of blood cell disorders
- have cancer affecting blood cells or bone marrow
- have abnormally low levels of certain white blood cells (neutrophils) in the body

- have a recent history of lung disorders such as pulmonary infiltrates or pneumonia
- are receiving high dose chemotherapy
- have osteoporosis (porous bones)
- are a donor undergoing peripheral blood progenitor cell mobilization, you should meet all the criteria for stem cell donation. The safety and efficacy of ZARZIO[®] have not been assessed in normal donors <16 years or >60 years
- have known bone marrow infiltrating infections or malignancy
- have HIV infection

- Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Especially tell your doctor if you take:

- 5-Fluorouracil, a medication used to treat cancer
- Lithium, which is used to treat bipolar disorders
- Anticancer drugs on the same day
- Any drugs that reduces the bone marrow activity to produce blood cells

How to use ZARZIO[®]

ZARZIO[®] injections can be given by a healthcare provider by intravenous (IV) infusion or under your skin (subcutaneous injection).

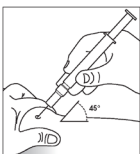
Your healthcare provider may decide subcutaneous injections can be given at home by you or your caregiver. If ZARZIO[®] is given at home, consult your healthcare provider on how to prepare and inject a dose of ZARZIO[®].

Instructions on how to inject ZARZIO[®] yourself.

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.

1. Wash your hands.
2. Remove one syringe from the pack and 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 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.
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 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 only for one injection.



The following information is intended for healthcare professionals only

The solution should be visually inspected prior to use. Only clear solutions without particles should be used. Accidental exposure to freezing temperatures does not adversely affect the stability of Zarzio.

Zarzio contains no preservative: In view of the possible risk of microbial contamination, Zarzio syringes are for single use only.

Dilution prior to administration (optional)

If required, Zarzio may be diluted in glucose 50 mg/ml (5%) solution. Zarzio must not be diluted with sodium chloride solutions.

Dilution to a final concentration < 0.2 MU/ml (2 mcg/ml) is not recommended at any time.

For patients treated with filgrastim diluted to concentrations < 1.5 MU/ml (15 mcg/ml), human serum albumin (HSA) should be added to a final concentration of 2 mg/ml.

Example: In a final volume of 20 ml, total doses of filgrastim less than 30 MU (300 mcg) should be given with 0.2 ml of human serum albumin 200 mg/ml (20%) solution Ph. Eur. added.

When diluted in glucose 50 mg/ml (5%) solution, filgrastim is compatible with glass and a variety of plastics including polyvinylchloride, polyolefin (a copolymer of polypropylene and polyethylene) and polypropylene. After dilution: Chemical and physical in-use stability of the diluted solution for infusion has been demonstrated for 24 hours at 2°C to 8°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at

2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Using the pre-filled syringe with a needle safety guard

The needle safety guard covers the needle after injection to prevent needle stick injury. This does not affect normal operation of the syringe. Depress the plunger slowly and evenly until the entire dose has been given and the plunger cannot be depressed any further. While maintaining pressure on the plunger, remove the syringe from the patient. The needle safety guard will cover the needle when releasing the plunger.

Using the pre-filled syringe without a needle safety guard

Administer the dose as per standard protocol.

Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

- **How much to use**

Your healthcare provider will tell you how much ZARZIO® to inject according to your clinical conditions.

Do not change your dose or stop ZARZIO® unless your healthcare provider tells you to do so. Take ZARZIO® exactly as your doctor tells you to take it.

- **When to use it**

Use as directed by your doctor or pharmacist.

- **How long to use it**

Continue taking ZARZIO® for as long as your doctor recommends.

- **If you forget to use it**

If you have missed an injection, or injected too little, talk to your doctor. Do not inject a double dose to make up for a forgotten dose.

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

- *If you use too much (overdose)*

You should inform the doctor immediately if you think too much ZARZIO® has been injected.

While you are using ZARZIO®

- *Things you must do*

Always follow your doctor's instructions carefully.

- *Things you must not do*

- Do not use ZARZIO® to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

- *Things to be careful of*

Driving and using machines

ZARZIO® may have minor influence on your ability to drive and use machines. This medicine may cause dizziness and caution is advised when driving and caution is advised when driving a car or operating machinery.

Side Effects

Like all medicines, ZARZIO® can cause side effects, although not everybody gets them.

Very common side effects include:

- Low levels of platelets and red blood cells
- Headache
- Diarrhea
- Nausea/vomiting
- Hair loss
- Musculoskeletal pain
- Tiredness
- Inflammation of digestive tract lining from mouth to anus (mucosal inflammation)
- fever

Common side effects include:

- Sepsis (blood infection)
- Inflammation or swelling of the bronchial tubes

- Upper respiratory tract infection
- Urinary tract infection
- Spleen enlargement
- Decreased red blood cells
- Decreased appetite
- Increased levels of lactate dehydrogenase and alkaline phosphate in blood
- Difficulty in sleep
- Dizziness
- Decreased sense of touch or sensation
- “pins-and-needles” sensation
- Increase or decrease in blood pressure
- Difficulty in breathing
- Cough
- Throat and mouth pain
- Bleeding from nose
- Constipation
- Liver enlargement
- Rash
- Redness of the skin
- Muscle contraction
- Blood in urine
- Coughing up of blood
- Painful or difficult urination
- Chest pain
- Pain
- Lack of energy
- General discomfort
- Swelling of limbs
- Transfusion reaction

These are not all of the possible side effects of ZARZIO®. For more information as your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5490, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)).

Storage and disposal of ZARZIO®

- *Storage*

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the box and on the label after the

letters EXP. The expiry date refers to the last day of that month.

- Store and transport refrigerated (2°C -8°C).
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- The product should be used immediately after dilution. It can be stored for a maximum of 24 hours at 2°C to 8°C.
- Patient may remove the product from the refrigerator and store it at room temperature (not above 25°C) for one single period of up to 8 days. At the end of this period, the product should not be put back in the refrigerator and should be disposed of.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- *What it looks like*

ZARZIO® is clear, colorless to slightly yellowish solution.

Pre-filled syringe (type I glass) with injection needle (stainless steel), with or without a needle safety guard, containing 0.5 ml solution.

Pack sizes of 1, 3, 5 or 10 pre-filled syringes. Not all pack sizes may be marketed.

- *Ingredients*

- *Active ingredient*
Filgrastim

- *Inactive ingredients*

Glutamic acid
Sorbitol (E420)
Polysorbate 80
Sodium hydroxide
Water for injection

- *MAL number(s)*

30MU/0.5ml

MAL12035084ACZ

Product registration holder

Sandoz Products Malaysia Sdn. Bhd.
Unit 1202, Level 12, Uptown 1,
No. 1, Jalan SS 21/58, Damansara
Uptown,
47400 Petaling Jaya, Selangor,
Malaysia

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