

Patient Information Leaflet

Granocyte™ Lenograstim

Please read this leaflet carefully before you take your medicine. It gives you important information about your medicine.

It does not contain all the information about your medicine you may need to know. If you have any questions, or are unsure about anything to do with your treatment, ask your doctor or pharmacist for more information.

What is in the pack?

The name of your medicine is Granocyte.

The pack contains two items:

A vial containing a powder and an ampoule or syringe (with two needles) containing a liquid.

The active ingredient in the Granocyte-34 vial is lenograstim 33.6 Million International Units (263 micrograms).

The active ingredient in the Granocyte-13 vial is lenograstim 13.4 Million International Units (105 micrograms).

The vial also contains these inactive ingredients:

mannitol, arginine, phenylalanine, methionine, polysorbate 20, and hydrochloric acid.

The ampoule contains 1.05 ml of Water for Injections, which is used to dissolve the powder in the vials before it is given.

The syringe contains 1.05 ml of Water for Injections, which is used to dissolve the powder in the vials before it is given.

Granocyte is available in the following pack sizes :

- 1 pack of 5x1 (13.4 MIU(105 µg)) vial + 5x1 (1 ml) prefilled syringe with solvent
- 1 pack of 1x1 (13.4 MIU(105 µg)) vial + 1x1 (1 ml) ampoule with solvent
- 1 pack of 5x1 (33.6 MIU(263 µg)) vial + 5x1 (1 ml) prefilled syringe with solvent
- 1 pack of 5x1 (33.6 MIU(263 µg)) vial + 5x1 (1 ml) ampoule with solvent.

What is in your medicine?

Granocyte is a blood cell growth factor: one of a group of medicines which increase the number of neutrophils in the blood. Neutrophils are a type of white blood cell which attack and kill the germs that cause infections. One of the problems caused by a low number of neutrophils is that infections are easily caught and can be very serious.

Who supplies Granocyte?

The Product Licence for Granocyte is held by Chugai Pharma UK Limited, Mulliner House, Flanders Road, Turnham Green, London W4 1NN.

Granocyte is made by Chugai Pharmaceutical Company Limited, 5-1 Ukima 5-Chome, Kita-ku, Tokyo 115 Japan.

The Product Licence for the Water for Injections pre-filled syringes is held by Chugai Pharma U.K.Limited, Mulliner House, Flanders Road, Turnham Green, London, W4 1NN.

The Water for Injections prefilled syringes are made by Vetter Pharma – Fertigung GMGH, Schutzenstrasse, 99/101, Postfach 2380, D-7980 Ravensburg, Germany.

The Product Licence for the Water for Injections ampoule is held by Aventis Pharma Ltd., West Malling, Kent, ME19 4AH.

The Water for Injections ampoule is made by Haupt Pharma Livron, 1 Rue Comte de Sinard, BP1 26250, Liveron, France.

When Is Granocyte Used?

Granocyte is used after bone marrow transplantation or after anti-cancer drugs, to shorten the time for which you have a low number of neutrophils, and shorten the time for which you may be at risk of catching an infection.

Granocyte also increases the number of immature blood cells in your blood, called stem cells, or progenitor cells. These cells can be extracted and collected using a blood processing machine. They can then be stored and transfused back at a later date to speed up the recovery of your blood after chemotherapy treatment.

Ask your doctor for any information you need.

Before you are given Granocyte

If the answer is **YES** to any of these questions, or you are not sure, discuss the matter with your doctor or pharmacist before taking any of the medicine.

- Do you have a condition called phenylketonuria?
- Do you have a myeloid cancer of the bone marrow?
- Are you pregnant, or could you be pregnant, or are you planning a pregnancy?
- Are you breast feeding?
- Do you have any kidney or liver problems?
- Do you have any pain in the abdomen or shoulder?
- Are you being given anti-cancer drugs on the same day as Granocyte?
- Is your doctor increasing the dose of your chemotherapy?
- Is your doctor reducing the time between your chemotherapy treatments?
- Have you had chemotherapy or radiotherapy before?
- Is the patient younger than two years old?

How is Granocyte given?

For bone marrow transplantation and stem cell collection after chemotherapy and after treatment with chemotherapy the dose is worked out by a calculation using your weight and height which gives your Body Surface Area in square metres (m²). The dose is normally 19.2 Million International Units (150 micrograms) per m² per day and is given as a single injection once a day. The doctor will work out your dose.

For stem cell collection without chemotherapy the dose is worked out using your weight. The dose is normally 10 micrograms per kg per day.

If you have had a bone marrow transplant, Granocyte may be given as an injection under the skin or as an infusion into a vein. If given as an infusion into a vein, Granocyte will be added to a small bag of fluid (either Sodium Chloride or dextrose solution) and given over about half an hour.

If you have had anti-cancer drugs or are having stem cells collected, Granocyte will usually be given as an injection under the skin.

Granocyte may be given from a few days to several weeks. It will not be given for longer than 28 days in a row.

Your doctor may give you Granocyte to take home and use yourself. The doctor or nurse will show you how to use it. You should take the medicine as your doctor has instructed and you should not try to inject yourself until you have been taught how to do it properly. The pharmacist's label will also tell you how much to use and how often. If it does not, or you are not sure, ask your doctor or pharmacist.

Does Granocyte have any side effects?

In trials in patients who have undergone bone marrow transplantation a number of side effects have been observed including swelling of the mouth, fever, diarrhoea, rash, abdominal pain, vomiting, hair loss, and infection. However such side effects may not be due to Granocyte and may be caused by other medicines taken during treatment.

In trials in patients with neutropenia as a result of chemotherapy, the following side effects have also been observed: hair loss, nausea, vomiting, fever and headache. These side effects are typical in cancer patients treated with chemotherapy. The use of Granocyte in combination with cytotoxic chemotherapy agents may also cause additional changes in your blood and your doctor may wish to carry out further blood tests in order to detect these.

While taking Granocyte you may also experience coughing, fever, and may easily become out of breath. Should these side effects occur you should tell your doctor immediately. In some people Granocyte can cause pain in the bones, abdomen or shoulder. Some people get redness and soreness at the site of injection. If either of these happens you should tell your doctor or pharmacist as soon as possible.

If you notice any other unusual signs, or feel unwell while being treated with Granocyte, tell your doctor or pharmacist immediately.

Expiry Date

Each vial of Granocyte and ampoule or syringe of Water for Injections has the expiry date on the label. They should not be used after this date. If this has passed, take them to your pharmacist who will dispose of them for you.

Storage

The shelf life of Granocyte is 2 years. Do not store above +30°C. Do not freeze.

If your doctor decides to stop treatment with Granocyte do not keep any of the vials, ampoules or syringes you may have left. Give them to your pharmacist who will dispose of them for you.

REMEMBER your doctor has prescribed Granocyte for you. Never give the vials to someone else to take, they may be harmed, even if their symptoms seem to be the same as yours.

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