GRANOCYTE® 34

Lenograstim

Powder and solvent for solution for injection or infusion in pre-filled syringes

Read all of this leaflet carefully before using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any questions or are unsure about anything, please ask your doctor or your pharmacist for more information.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. WHAT Granocyte Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes IS AND WHAT IT IS USED FOR

The name of your medicine is Granocyte, powder and solvent for solution for injection or infusion in pre-filled syringes (called Grancocyte in this Package Leaflet).
Granocyte contains an active ingredient called lenograstim and belongs to the group of medicines known as cytokines.

Granocyte helps your body to produce more white blood cells, thus helping you to fight infection.
- These white blood cells are produced in your bone marrow.
- Granocyte stimulates your bone marrow, making it produce more cells known as "blood stem cells".
- It then helps these immature blood cells to become fully functional mature blood cells.
- In particular, it helps in the production of white blood cells called neutrophils. Neutrophils are important in fighting infection.

Granocyte is used:

- **after anticancer treatment, if the number of white blood cells you have is too low** (this condition is called **neutropenia**)

Some anticancer treatments (also known as chemotherapy) affect your bone marrow. This causes a decrease in the number of white blood cells you have. More precisely, this decrease affects the neutrophils and is called neutropenia. It lasts until your body is able to produce more white blood cells. When the number of neutrophils is low, it is easier to get an infection. Certain infections can sometimes be very serious. Granocyte will help to reduce the duration of neutropenia by stimulating your body so that it creates new white blood cells.
- **when it is necessary to increase the number of blood stem cells you have** (this process is called **mobilization**)

Granocyte can be used to stimulate your bone marrow so that it produces more blood stem cells. This is called mobilization. Granocyte can be used alone or possibly after chemotherapy. The blood stem cells are removed from your blood and collected with a special machine (a process known as cytapheresis). They can then be stored and given back to you during blood transfusion.
- **after bone marrow or blood stem cell transplantation**

If you need bone marrow or blood stem cell transplantation, you will first receive high-dose chemotherapy or total body irradiation. This is to remove the diseased cells from your body. The bone marrow or blood stem cell transplantation will then be carried out using blood transfusion. It will take some time for your bone marrow to start producing new blood cells, including white blood cells. Granocyte will help your body to produce new white blood cells more quickly.
- **when you wish to donate your blood stem cells**

Granocyte can also be used by healthy donors. In this case, it is used to stimulate the bone marrow so that extra blood stem cells can be produced. This is called mobilization (see above). Healthy donors can then donate their blood stem cells to somebody who needs them.

2. BEFORE USING Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes

Never use Granocyte and tell your doctor if:
- you are allergic (hypersensitive) to lenograstim or to one of the other ingredients of Granocyte listed in Section 6 below. The signs of an allergic reaction include skin rash, breathing or swallowing problems, and swollen lips, face, throat or tongue.
- you have a condition called phenylketonuria.
- you have a type of cancer called myeloid cancer. However, you can be given Granocyte in some cases, if you have recently been diagnosed with acute myeloid leukemia and if you are over 55 years old.
- you have chemotherapy on the same day.

Do not use this medicine if one of the above applies to you. If you are unsure, ask your doctor or pharmacist for advice before using Granocyte.

Take special care with Granocyte Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes:

Before using this medicine, check with your doctor or pharmacist:
- which diseases you have had, especially allergies, infections and kidney or liver problems.

If you are unsure, talk to your doctor or pharmacist before using Granocyte.

Taking/using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken another medicine, including an over-the-counter medicine or a herbal medicine.

If you wish to donate your blood stem cells and you are under anticoagulant treatment (such as warfarin or heparin), make sure that you tell your doctor before starting treatment with Granocyte. Similarly, tell him/her if you have other blood clotting problems.

If you are receiving anticancer chemotherapy, do not use Granocyte during the period from 24 hours before your chemotherapy to 24 hours afterwards.

Pregnancy and breast-feeding
Granocyte has not been studied in pregnant or breast-feeding women. Do not use this medicine if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding, unless your doctor or pharmacist tells you it is necessary.

If you are likely to become pregnant, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
The effect of Granocyte on the ability to drive and use machines is not known. Wait and see what effect it has on you before driving or using tools or machines.

Important information about some of the ingredients of Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes
Granocyte contains phenylalanine, which may be harmful for you if you have a condition known as phenylketonuria (see "Never use Granocyte and tell your doctor if").

3. HOW TO USE Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes

Granocyte must only be given with monitoring by a specialized cancer and/or blood clinic. It is usually given by a nurse, as a subcutaneous injection or an infusion.
However, some patients are instructed to give their own injections. For any questions about how to administer this medicine, talk to your doctor, nurse or pharmacist.

Dosage, frequency of administration and duration of treatment
If you do not know why you are being given Granocyte, or if you have any questions about the dose to be used, talk to your doctor, nurse or pharmacist.
After bone marrow transplantation, chemotherapy or mobilization of blood stem cells after chemotherapy
- Your doctor will fix the dose you will receive based on your body surface area, which will be calculated using your height and weight. It will be expressed in m2.
- The usual Granocyte dose is 150 micrograms per m2 of body surface area per day.
- Your doctor will decide how long you will be given Granocyte for. The maximum treatment period is 28 days.
- If you are receiving Granocyte for mobilization of blood stem cells after chemotherapy, your doctor will tell you when your blood stem cells will be collected.

For mobilization of blood stem cells with Granocyte only
- Your doctor will fix the dose you will receive based on your weight.
- The usual Granocyte dose is 10 micrograms per kg of your body weight per day.
- You will be given Granocyte as an injection under the skin for 4 to 6 days.
- Your blood stem cells will be collected 5 to 7 days after starting treatment.

Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes is given to patients with a body surface area of up to 1.8 m2.

If you use more Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes than you should:
If this medicine is given to you by a healthcare professional, you are unlikely to receive an excessive dose of Granocyte. Your progress during treatment and the dose will be monitored. Ask this healthcare professional if you do not understand why you have been given this dose.
If you have used too much Granocyte, contact a doctor or immediately go to a hospital. Bring the box of medicine with you so that the doctor knows what you have taken. If the dose used is too high, you may have harmful side effects. The problems you are most likely to experience are muscle and bone pain.

If you forget to use Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes :
Do not use a double dose to make up for the dose you have not been given. Talk to your doctor and he/she will tell you what to do.
If you stop taking Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes :
Blood tests:
Treatment with this medicine requires monitoring by a doctor. Regular blood tests are necessary for your doctor to check the amount of the different blood cells (neutrophils, other white blood cells, red blood cells and platelets in your body).
Other blood tests that could be requested by other doctors during treatment with Granocyte can indicate changes in your blood. It is important to tell the doctor who prescribed these tests that you are being treated with Granocyte. The number of white blood cells may increase, the number of platelets may decrease and the level of enzymes may increase. These changes usually improve as soon as Granocyte treatment is stopped. If you have other questions about using this medicine, ask your doctor or pharmacist for more information.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Granocyte 34 million IU/ml, powder and solvent for solution for injection or infusion in pre-filled syringes can cause side effects, although not everybody experiences them.

Stop taking Granocyte and tell your doctor if:
- you have pain in the upper left-hand side of your abdomen or in your left shoulder. It could be a sign of a swollen spleen. This is a common side effect, but it only leads to spleen rupture in very rare cases.
- you have an allergic reaction. In this case, the signs include skin rash, breathing or swallowing problems, and swollen lips, face, throat or tongue. This is a very rare side effect.
- you have a very serious reaction called anaphylactic shock. In this case, you may have a feeling of faintness, weakness, difficulty breathing, and swollen face. This is a very rare side effect.
- you have breathing problems, involving coughing and fever, or you feel that you are easily out of breath. This is a rare side effect.

Contact your doctor or pharmacist as soon as you have one of the following side effects:
- a reaction at the site of injection. This is a common side effect.
- skin problems, such as reddish swelling on your arms, legs and sometimes your face and neck, along with fever (signs of Sweet's syndrome). You may also have red vesicles, along with fever and headache (signs of Lyell's syndrome). There may be other skin problems such as swollen bruising on your legs or ulcers on your body, along with fever and joint pain. These are very rare side effects.

Other side effects:
- bone and muscle pain, headache. These are common side effects. If they occur, pain can be relieved with conventional painkillers.

Healthy blood stem cell donors

If you have been given Granocyte for blood stem cell donation, you may feel tired after donating these cells. This is a very common side effect. It is due to the drop in the number of red blood cells and platelets you have. The number of your red blood cells and platelets will return to normal during the days following the donation.

If any of the side effects becomes serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Granocyte

Keep out of the reach and sight of children.

Do not use any constituent of Granocyte (i.e. powder or solvent for solution) after the expiry date. The expiry date for Granocyte powder is stated on the outer packaging and on the label of each Granocyte vial. The expiry date for the solvent (water for injection) is indicated either on the label of each ampoule containing water for injection or on the pre-filled syringe and blister pack.

The expiry date is the last day of the month.

Do not store above +30°C.

Do not freeze.

After reconstitution or dilution of Granocyte, immediate use is recommended. If necessary, you can keep the reconstituted or diluted solution for 24 hours at a temperature between +2°C and +8°C (in a refrigerator).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Granocyte contains:

The active ingredient is:
Lenograstim (rHuG-CSF).....(33.6 million IU, equivalent to 263 µg) per ml after reconstitution.

The other ingredients are:
Arginine, phenylalanine, methionine, mannitol (E 421), polysorbate 20 and dilute hydrochloric acid.
Ingredient with specific effect: phenylalanine.
The solvent used to reconstitute the solution is water for injection.

What Granocyte looks like and contents of the pack
Granocyte is available as a powder and solvent for solution for injection or infusion in pre-filled syringes.
Powder (vial) + 1 ml of solvent (pre-filled syringe) + 2 needles (1large, beige needle (19 G) intended for reconstitution + 1 small, brown needle (26 G) for administration).
Granocyte is available in boxes of 1 or 5.
Not all pack sizes may be marketed.

Manufacturer
SANOFI WINTHROP INDUSTRIE
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FRANCE

This Package Leaflet was last approved on february 2009.

The following information is intended for healthcare professionals only:
Practical information for healthcare professionals when preparing and handling the medicinal product.
Granocyte vials are for single use. **Due to the possible risk of microbial contamination, pre-filled syringes of solvent are for single use only.**
Granocyte is to be administered subcutaneously or intravenously.
Preparation of the reconstituted Granocyte solution
- Aseptically add the extractable contents of one pre-filled syringe to the Granocyte vial using the 19G needle.
- Shake gently until **completely dissolved**.
- Do not shake vigorously.
- The reconstituted parenteral solution should be clear and free of particles. Remove the required volume of reconstituted solution from the vial using the 19G needle.
- Administer immediately by subcutaneous injection using the 26G needle.

For intravenous use, Granocyte must be diluted after reconstitution.
Granocyte is compatible with the commonly used administration sets for injection when diluted:

- in a 0.9% sodium chloride solution (in PVC bags or glass bottles),
- or in a 5% glucose solution (in glass bottles).

Dilution of Granocyte 34 million IU/ml to a final concentration of less than 0.32 million IU/ml (2.5 µg/ml) is not recommended. One vial of reconstituted Granocyte 34 million IU/ml should not be diluted in more than 100 ml.

Any unused medicine, solution or waste product must be disposed of as per current regulations.