GRANOCYTE®

Lenograstim (len-o-GRA-stim)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GRANOCYTE®. 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 being given GRANOCYTE® against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What GRANOCYTE® is used for

GRANOCYTE® is a synthetic (man-made) version of a substance called granulocyte colony-stimulating factor (G-CSF) which is produced naturally by the human body.

G-CSF is produced by certain cells within the bone marrow to stimulate the production of neutrophils (a type of white blood cell). Neutrophils help the body to prevent or fight infection. A low neutrophil level increases your risk of infection. GRANOCYTE® is therefore used to (help) increase the neutrophil count in those with low white blood cell counts, a condition known as neutropenia.

A low number of neutrophils in your blood (neutrophil count) often occurs after bone marrow transplantation or chemotherapy. On rare occasions, infants have a low neutrophil count present at birth (congenital neutropenia).

Stem Cell Transplantation
Some chemotherapy drugs have toxic effects on the bone marrow. Your doctor may collect stem cells (the parent cells of all blood cells) from your blood before you have chemotherapy.

There are normally only a small number of stem cells in the blood. GRANOCYTE® can be used to increase the number of stem cells in the blood. The stem cells are then collected by a procedure, called leukapheresis, done in hospital.

The stem cells collected from the blood are stored until after you have had your chemotherapy. They are then given back to you to replace those cells destroyed by the chemotherapy drugs. This is known as a stem cell transplantation. You may also be given GRANOCYTE® after your stem cell transplantation to help speed up your recovery.

GRANOCYTE® can also be used in healthy donors in order to collect their stem cells for transplantation into patients.

Bone Marrow Transplantation
Bone marrow transplantation is a procedure used to treat certain types of cancers, especially those that originate in the bone marrow (leukaemia). It involves destroying your bone marrow with chemotherapy and/or radiotherapy and replacing it with a bone marrow graft either from yourself or a donor. The neutrophil count will fall to a very low level soon after you receive your transplant.

GRANOCYTE® is used after bone marrow transplantation to speed up the increase in your neutrophil count to reduce your risk of developing an infection.

Chemotherapy
Chemotherapy is used to destroy cancer cells. Sometimes chemotherapy also destroys other cells, such as neutrophils. This may increase your risk of infection.

GRANOCYTE® is used after chemotherapy to increase the neutrophil count. This will reduce the likelihood of infection.

Congenital Neutropenia
Children born with low neutrophil count suffer frequently from infections. This is called congenital neutropenia. On occasions, the infection may be severe, requiring hospitalisation and intravenous antibiotics.

GRANOCYTE® is used in patients with congenital neutropenia to raise and maintain the neutrophil count and hence reduce the likelihood of 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 reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you are given GRANOCYTE®

When you must not be given it

You must not be given GRANOCYTE® if you have an allergy to:

- any medicine containing lenograstim
- any of the ingredients listed at the end of this leaflet.

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.

You must not be given this medicine if you have any of the following medical conditions:

- myelodysplasia (an abnormality of bone marrow cells),
- acute myeloid leukaemia (AML) (a cancer of bone marrow cells), or
- chronic myeloid leukaemia (CML) (a cancer of bone marrow cells).

There is a possibility that GRANOCYTE® may promote the growth of these abnormal cells. If you have any concerns about this, talk to your doctor.

You must not be given GRANOCYTE® if you are currently receiving chemotherapy medicines.
GRANOCYTE® is normally started on the day after chemotherapy is finished; or on the day after your bone marrow transplant or stem cell transplant.

You must not be given GRANOCYTE® if you are a healthy donor and you are over 60 years of age or under 18 years of age.
The safety and effectiveness of GRANOCYTE® in healthy donors in these age groups have not been studied.

Do not use GRANOCYTE® if the vial has been used before.
GRANOCYTE® vials are intended for single-use only. They do not contain a preservative and there is a possibility of contamination with repeated use. Any unused GRANOCYTE® should be discarded.

Do not use GRANOCYTE® if you have prepared the solution and it has not been stored in a refrigerator.
As GRANOCYTE® does not contain a preservative, there is a risk that any prepared solution that has not been stored in a refrigerator may be contaminated with germs and cause an infection.

Do not use if you have prepared the solution of GRANOCYTE® more than 24 hours ago (even if stored in a refrigerator).

Do not use if the solution of GRANOCYTE® is not clear and colourless, or it contains particles.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering, or if the vial cap shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

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

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

- kidney disease, or are undergoing dialysis
- liver disease
- sickle cell disease or a similar blood disease

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved. It is not known whether GRANOCYTE® is excreted in human milk.

If you have not told your doctor about any of the above, tell him/her before you are given GRANOCYTE®.

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 GRANOCYTE® may interfere with each other. These include:

- medicines used to treat cancer (cytotoxic chemotherapy).

These medicines may be affected by GRANOCYTE® or may affect how well it works. It is recommended that GRANOCYTE® should start on the day following completion of chemotherapy.

Your doctor and pharmacist have more information on medicines to be careful with

or avoid while being treated with this medicine.

How GRANOCYTE® is given

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

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

How much is given

Your doctor will decide what dose you will receive. This will depend on your condition, your body weight and the number of white blood cells (neutrophils) in your blood.

How it is given

Dissolve each vial of GRANCOCYTE with 1.0mL sterile Water for Injections before use.

GRANOCYTE® is given as an injection into a vein or an injection under the skin.

GRANOCYTE® may be given to you by a doctor or nurse while you are a hospital in-patient, or attending an out-patient clinic. Alternatively, you may be able to receive injections of GRANOCYTE® at home. In such cases, you or your carer will be taught how to inject GRANOCYTE® under the skin (subcutaneously). Be sure to inject the exact dose that your doctor has prescribed.

If you will be self-administering GRANOCYTE® your doctor or nurse will provide you with proper training and instruction on how to prepare your injection, and where and how to do the injection.

How long it is given

Your doctor will tell you how many days you will need to receive treatment with GRANOCYTE®.

Continue treatment with your medicine for as long as your doctor tells you.
It is important that you continue to receive your medicine even if you feel well.

The duration of use varies according to your condition:

- if you are having a bone marrow transplant or stem cell transplant, usually only one course of GRANOCYTE® is required
- if you are a healthy donor of stem cells, usually only one course of GRANOCYTE® is required (with a maximum of 28 consecutive days of treatment)
- if you are having chemotherapy, your doctor may prescribe several courses of treatment with GRANOCYTE®
- if you have congenital neutropenia, your doctor may prescribe continuous or intermittent treatment with GRANOCYTE®.

If you forget to have your injection

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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 or pharmacist.

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

If you receive too much (overdose)

If you think that you or anyone else may have been given too much Granocyte® tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital or immediately contact the Poisons Information Centre for advice on management. (In Australia, call 13 11 26). Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Ask your doctor or pharmacist if you have any concerns.

While you are being given GRANOCYTE®

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given GRANOCYTE®.

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

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are being given 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.
Your doctor will do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Measure your temperature every day, and be alert for other signs of an infection.
Do this before your injection of GRANOCYTE®. You should watch for fever - a temperature of 38.2°C or greater, or as your doctor suggests. Your body's ability to fight infection is reduced and it is therefore very important that you look for signs or symptoms of infection. Signs or symptoms of infection include:

- fever
- chills
- shaking
- sweating, especially at night.

If you notice any signs or symptoms of infection, tell your doctor immediately or go to accident and emergency at your nearest hospital.

Things you must not do

Do not take GRANOCYTE® 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 giving your injections or lower the dosage without checking with your doctor.
For GRANOCYTE® to work properly, you have to use it exactly as your doctor has instructed.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with GRANOCYTE®.
This medicine helps most people with a low white blood cell count, but it may have unwanted side effects in a few people. 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.

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, nurse or pharmacist if you notice any of the following.:

- bone pain, back pain
- painful, swollen joints
- aching muscles, muscle tenderness or weakness not caused by exercise
- headache and nausea
- redness, soreness or itchiness around an injection site
- loss of energy or strength
- fever

Tell your doctor or nurse as soon as possible if you notice any of the following:

- skin rash
- skin reactions, including tender or painful areas or ulcers, blisters, or peeling
- bleeding or bruising more easily than normal
- red or purple spots on your skin
- cough, fever and difficulty in breathing
- abnormal swelling of the limbs (e.g. legs and feet)
- pink or dark rust coloured urine
- bubbly and foamy urine
- puffiness in face and/or swelling of ankles

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- shortness of breath
- lightheadedness, dizziness or fainting
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- coughing up blood

The above list includes very serious side effects. If you have them, you may have had an allergic reaction to GRANOCYTE®. You may need urgent medical attention or hospitalisation.

If you are or have been given GRANOCYTE® for the collection of stem cells, tell your doctor immediately if you develop pain in the upper left side of your stomach or in your shoulder.

If you are a healthy donor, and you are or have been given GRANOCYTE® for the collection of stem cells, tell you doctor

immediately if you notice any of the following:

- inflammation of the coloured part of the eye
- chest pain
- collapse, numbness or weakness of the arms or legs
- headache, dizziness or confusion, visual disturbances
- difficulty swallowing, slurred speech or loss of speech
- gum bleeding or frequent bruising
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- signs of anaemia such as tiredness, being short of breath when exercising and looking pale
- swollen glands in the neck, armpit or groin.

These are serious side effects. These effects have been reported rarely in healthy donors taking GRANOCYTE®, and it is not known whether these are definitely caused by GRANOCYTE®.

If you or your child are being treated long term for congenital neutropenia, tell your doctor immediately if you develop any of the following:

- rash or unusual changes to the skin
- unusual bleeding or bruising.

Some patients may get an enlarged spleen, changes in the number of certain blood cells or bone thinning. Your doctor will monitor you for the appearance of these side effects.

Very rarely, some forms of leukaemia and chromosome disorders have occurred in patients with congenital neutropenia treated with G-CSF. It is not known if this was due to the congenital neutropenia or to the G-CSF. Your doctor will do tests to check for these conditions.

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

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

Storage and disposal

Storage

GRANOCYTE® will be stored in the pharmacy or on the ward in a cool dry place where the temperature stays below 30°C.

Once GRANOCYTE® is dispensed to you, keep it in a place where the temperature stays below 30°C. Short exposure of the vials to elevated temperatures (up to 4 weeks at 40°C) does not affect the product stability.

Do not store GRANOCYTE® in the freezer.
Freezing can damage some medicines.

Keep prepared solutions of GRANOCYTE® in the refrigerator at a temperature between 2−8°C for no longer than 24 hours.
As GRANOCYTE® does not contain a preservative, there is a risk that any solution prepared more than 24 hours ago may be contaminated with germs and cause an infection.

Keep this medicine in the original pack until it is time to use it.
If you take it out of the pack, it may not keep well.

Do not store GRANOCYTE® or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine, or the expiry date on the vials has passed, or the prepared solution of GRANOCYTE® has been left unrefrigerated, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

GRANOCYTE® is a white powder in a glass vial. It is available in two different dosage strengths:

- **GRANOCYTE® 34 -** 263 micrograms (33.6 million International Units) of lenograstim per vial
- **GRANOCYTE® 13 -** 105 micrograms (13.4 million International Units) of lenograstim per vial.

Ingredients

GRANOCYTE® 34 contains 263 micrograms (33.6 million International Units) of lenograstim as the active ingredient.

GRANOCYTE® 13 contains 105 micrograms (13.4 million International Units) of lenograstim as the active ingredient.

It also contains:

- D-Mannitol
- polysorbate 20
- L-Phenylalanine
- L-Methionine
- L-Arginine.

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

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

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