

Filgrastim Injection

“Human granulocyte Colony Stimulating Factor”

Filgrastim SEDICO

*Recombinant human granulocyte-colony stimulating factor
(rhG-CSF)....300 microgram.*



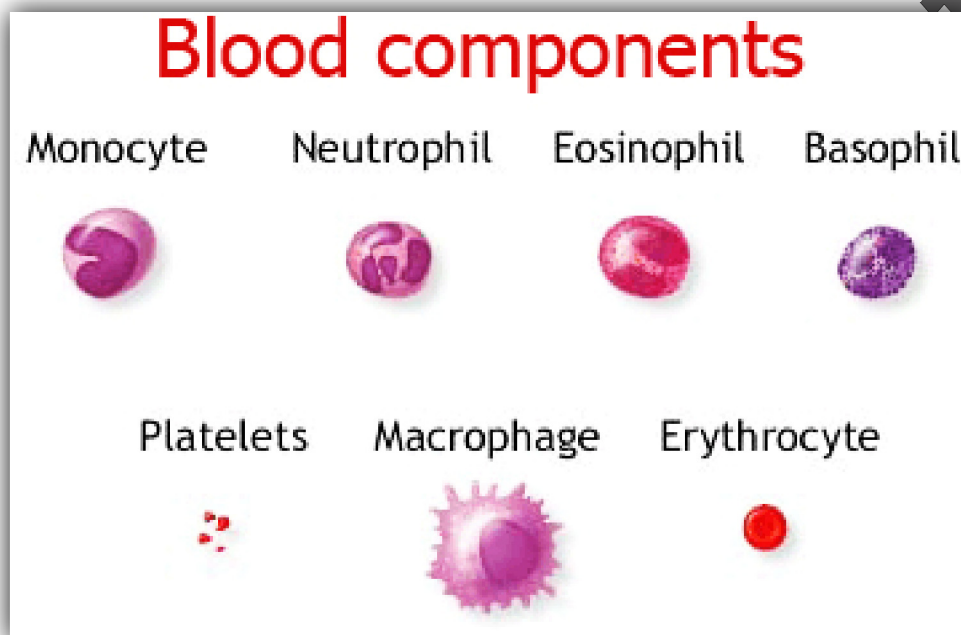
Pharmacology:

Filgrastim is a protein produced by DNA genetic recombination technology using E.Coli bacteria.

It stimulates the generation of neutrophils within bone marrow, accelerates the recovery of their count for the appropriate clinical response. Compared with natural products, its vitro biological activity and vivo are consistent.

What is Granulocyte?

Granulocytes are a category of white blood cells characterized by the presence of granules in their cytoplasm. They are also called polymorph nuclear leukocytes (PMN or PML) because of the varying shapes of the nucleus, which is usually lobed into three segments. In common parlance, the term polymorph nuclear leukocyte often refers specifically to neutrophils granulocytes, the most abundant of the granulocytes. Granulocytes or PMN are released from the bone marrow by the regulatory complement proteins.



Classification:

There are three types of granulocytes, distinguished by their appearance under Wright's stain:

- ▶ Neutrophil granulocytes (a type of blood cell needed to fight infection)
- ▶ Eosinophil granulocytes
- ▶ Basophil granulocytes

Their names are derived from their staining characteristics; for example, the most abundant granulocyte is the neutrophils granulocyte, which has neutrally-staining cytoplasmic granules.

What is Filgrastim?

Filgrastim is a granulocyte colony-stimulating factor (G-CSF) analog used to stimulate the proliferation and differentiation of granulocytes. It is produced by recombinant DNA technology. The gene for human granulocyte colony-stimulating factor is inserted into the genetic material of *Escherichia coli*.

The G-CSF then produced by *E. coli* is only slightly different from G-CSF naturally made in humans.

Why is this medication prescribed?

Filgrastim is used to decrease the chance of infection in people who have certain types of cancer and are receiving chemotherapy medications that may decrease the number of neutrophils, in people who are undergoing bone marrow transplants, and in people who have severe chronic neutropenia (condition in which there are a low number of neutrophils in the blood).

Filgrastim is also used to prepare the blood for leukapheresis.

Filgrastim is in a class of medications called colony-stimulating factors. It works by helping the body make more neutrophils.

How should this medicine be used?

Filgrastim comes as a solution (liquid) to inject under the skin or into a vein. It is usually given once a day, but may be given twice a day when it is used to treat severe chronic neutropenia. The length of your treatment depends on the condition that you have and how well your body responds to the medication. If you are using Filgrastim to decrease the risk of infection during chemotherapy, you will receive your first dose of Filgrastim at least 24 hours after you receive a dose of chemotherapy, and will continue to receive the medication every day for up to 2 weeks.

- If you are using Filgrastim to **decrease the risk of infection during a bone marrow transplant**, you will give the medication at least 24 hours after chemotherapy and at least 24 hours after the bone marrow is infused.

- If you are using Filgrastim to **prepare your blood for leukapheresis**, you will give the first dose of Filgrastim at least 4 days before the first leukapheresis and will continue to give the medication until the last leukapheresis.
- If you are using Filgrastim to **treat severe chronic neutropenia**, you may need to give the medication for a long period of time. If you are using Filgrastim to treat severe chronic neutropenia, you should know that Filgrastim will control your patient condition but will not cure it. Do not stop taking Filgrastim .

Other uses for this medicine:

Filgrastim is also used to decrease the chance of infection in people who have human immunodeficiency virus (HIV) or people who are taking certain medications that decrease the number of neutrophils.

What special precautions should the patient follow?

Before using Filgrastim:

- ▶ Checking for the allergy to Filgrastim, pegfilgrastim (Neulasta)
- ▶ Medications made from E. coli bacteria, or any other medications. Checking for the allergy to the medication since it is made from E. coli bacteria.
- ▶ If the patient takes any prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products or containing lithium (Eskalith, Lithobid) . the doses of medications should be changed or monitored.
- ▶ Doctor should know if the patient being treated with radiation therapy or has or have ever had chronic myeloid leukemia , myelodysplasia , or an enlarged spleen .
- ▶ Patient with sickle cell disease is more likely to have a crisis during the treatment with Filgrastim. Drink plenty of fluids during taken the medication.
- ▶ Pregnancy or planning to become pregnant or breast-feeding women should be declare by the woman patient.
- ▶ Using Filgrastim should be declared if the patient will has any surgery, including dental surgery.

Filgrastim decreases the risk of infection, but does not prevent all infections that may develop during or after chemotherapy. developing signs of infection such as fever; chills; rash; sore throat; diarrhea; or redness, swelling, or pain around a cut or sore should be announced.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What side effects can this medication cause?

Filgrastim may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- ▶ Redness
- ▶ Swelling
- ▶ Bruising
- ▶ Itching or a lump in the place where the medication was injected .
- ▶ Bone, joint, or muscle pain
- ▶ Headache
- ▶ Nosebleeds

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- ▶ Fever
- ▶ Trouble breathing
- ▶ Wheezing
- ▶ Rash
- ▶ Unusual bruising or purple markings under the skin
- ▶ Pain in the left upper part of the stomach or the tip of the left shoulder
- ▶ Shortness of breath
- ▶ Fast breathing
- ▶ Itching
- ▶ Swelling around the mouth or eyes
- ▶ Dizziness
- ▶ Hives
- ▶ Sweating

What storage conditions are needed for this medicine?

Keep this medication in the container it came in, tightly closed, and out of reach of children.

Store Filgrastim in the refrigerator but do not freeze it. If you accidentally freeze the medication, you may allow it to thaw in the refrigerator. However, if you freeze the same syringe or vial of medication a second time, you should throw away that syringe or vial.

Filgrastim may be kept at room temperature for up to 24 hours but should be kept away from direct sunlight. Throw away any medication that is outdated or no longer needed.