Amgofil®
Recombinant Human Granulocyte Colony Stimulating Factor
rhG-CSF

1. What Amgofil 300mcg is used for?

Amgofil is 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 (a type of blood cell needed to fight infection).

It is used for the following indications:

- Amgofil is used in people who are undergoing bone marrow transplants, in people who have severe chronic neutropenia (condition in which there are a low number of neutrophils in the blood), and to prepare the blood for leukapheresis (a treatment in which certain blood cells are removed from the body and then returned to the body following chemotherapy).
- Filgrastim is also used to increase the chance of survival in people who have been exposed to harmful amounts of radiation, which can cause severe and life-threatening damage to your bone marrow.
- Amgofil is in a class of medications called colony-stimulating factors. They work by helping the body make more neutrophils.

2. Before Amgofil 300mcg is administered to you:

Amgofil 300mcg should not be used:

- If you have known hypersensitivity to *Escherichia coli* derived proteins, to rhG-CSF or any component of the drug.

Special care should be taken with Amgofil 300mcg:

- It should be used with caution in patients with malignant hyperplasia of the bone marrow system (acute granulocytic leukemia).
- Blood levels especially neutrophils should be monitored twice a week.
- Long term safety has not been established. Although no allergic reactions have been reported with use of rhG-CSF in clinical trials, few cases of allergic reactions have been reported in a similar drug (incidence rate 1 : 4,000). These reactions were skin eruptions, urticarial, face swelling, dyspnea, tachycardia and hypotension. If these reactions occur, stop the drug and appropriate measures should be instituted.

Special Precautions:

Pregnancy
There is no adequate & well controlled clinical data in pregnant women. Use only when clearly indicated, taking into account the importance of the drug to the mother.

Breast-Feeding
It has not been studied if rhG-CSF is excreted in human milk. Exercise caution in administering the drug to a nursing mother.

Use in children
Safety data indicate that rhG-CSF does not exhibit any greater toxicity in children than adults.

Impairment in fertility, cancer causing or mutation causing potential
rhG-CSF cancer causing potential has not been studied. Though it failed to induce bacterial gene mutation in either the presence or absence of a drug metabolizing enzyme system. rhG-CSF had no effect in fertility of male or female rats, or on gestation.

3. How Amgofil is administered to you?

Method and routes of administration

- To be administered intravenously or subcutaneously
- It should not be administered in the period 24 hours before through 24 hours after the administration of cytotoxic chemotherapy because of the potential sensitivity of rapidly dividing myeloid cells to these agents.

Dosage:

- Dosage and administration time of rhG-CSF injection is decided according to the intensity of chemotherapy and declining degree of neutrophilic granulocytes as follows.

Condition/Parameters	Dosage	Remarks
Patients with low dose chemotherapy or whose estimated damage of marrow suppression is not serious	1.25 µg/kg body weight / day	Use until number of neutropenic granulocytes is within safe range (ANC > 5,000/mm^3)
Patients with high intensity chemotherapy or obvious decline of granulocytes	2.5 µg/kg body weight for 7 days	Withdraw administration when neutrophilic granulocytes restored to > 5,000/mm^3
Patients whose neutrophils have obviously declined (< 1,000/mm^3) after chemotherapy until granulocytes restored to above 5,000/mm^3	5 µg/kg body weight / day	
Or as prescribed by physician		
Withdraw administration when level of neutrophils is stable and monitor patients' condition		

Information Stability

- Do not dilute with saline at any time as product may precipitate.
- Inspect parenteral drug products visually for particulate matter and discoloration prior to use. Do not use if particulates or discolorations are observed.
- rhG-CSF is supplied in single use vials. Do not re-enter vials. Discard unused portions. Do not save unused drug for later administration.

Amgofil post administration effects:

Monitor the complete blood and platelet count twice weekly during therapy.

Discontinue rhG-CSF if the absolute neutrophil count exceeds 10,000/mm3 after the expected chemotherapy induced neutrophil nadir.

4. <u>Possible Side Effects</u>

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

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

- Pain in the left upper part of the stomach or the tip of the left shoulder
- Fever
- Shortness of breath

- Trouble/fast breathing
- Wheezing
- Dizziness
- Sweating
- Hives
- Rash
- Itching
- Swelling around the mouth, face, eyes, stomach, feet, ankles, or lower legs
- Unusual bruising or purple markings under the skin
- Unusual bleeding or bruising
- Nosebleeds
- Decreased urination
- Tiredness

These symptoms usually disappear upon withdrawal.

Some people who used Filgrastim to treat severe chronic neutropenia developed leukemia (cancer that starts in the bone marrow) or changes in the bone marrow cells that show that leukemia may develop in the future. People who have severe chronic neutropenia may develop leukemia even if they do not use Filgrastim. There is not enough information to tell if Filgrastim increases the chance that people with severe chronic neutropenia will develop leukemia. Talk to your doctor about the risks of using this medication.

5. Storing Amgofil 300mcg

- Store at 2 – 8 deg C.
- Keep this medication in the container it came in, tightly closed, and out of reach of children.
- Store Filgrastim in the refrigerator. If you accidentally freeze Filgrastim, you may allow it to thaw in the refrigerator. However, if you freeze the same syringe or vial of Filgrastim the 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.
- Single use only. Discard unused portion

6. Further information

Formulation

Each vial contains:

Recombinant Human G-CSF (rhG-CSF) =	300 µg
Acetic acid sodium acetate buffer =	10 nM
Mannitol =	5%
Tween-80 =	0.004%

Availability

rhG-CSF Amgofil 300µg/ml solution for injection in box of 1's.

Manufactured by:

Beijing SL Pharmaceutical Co. Ltd.
China

Imported & marketed by:

AMGOMED