

## **PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

S4

### **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**NEULASTIM®** Injection

### **Read all of this leaflet carefully before you start using this medicine**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.

NEULASTIM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **WHAT NEULASTIM CONTAINS**

NEULASTIM pre-filled syringes contain the active ingredient, Pegfilgrastim.

Each pre-filled syringe contains 6 mg Pegfilgrastim in 0,6 ml solution.

The other ingredients are sodium acetate, sorbitol (E420), polysorbate 20 and water for injections.

### **WHAT NEULASTIM IS USED FOR**

NEULASTIM contains the active substance pegfilgrastim. Pegfilgrastim is a protein produced by biotechnology. It belongs to a group of proteins called cytokines, and is very similar to a natural protein (granulocyte-colony stimulating factor) produced by your own body.

NEULASTIM is used to reduce the duration of neutropenia (low white blood cell count) and the occurrence of febrile neutropenia (low white blood cell count with a fever) which can be caused by the use of cytotoxic chemotherapy (medicines that destroy rapidly growing cells). White blood cells are important as they help your body fight infection. These cells are very sensitive to the effects of chemotherapy which can cause the number of these cells in your body to decrease. If white blood cells fall to a low level there may not be enough left in the body to fight bacteria and you may have an increased risk of infection.

Your doctor has given you NEULASTIM to stimulate your bone marrow (part of the bone which makes blood cells) to produce more white blood cells that help your body to fight infection.

### **BEFORE TAKING NEULASTIM**

NEULASTIM is for use in adults aged 18 and over.

### **Do not use NEULASTIM:**

- if you are hypersensitive (allergic) to pegfilgrastim, filgrastim, *E. coli* derived proteins, or any of the other ingredients of NEULASTIM.

### **Please tell your doctor**

- if you experience a cough, fever and difficulty in breathing;
- if you have sickle cell anaemia;
- if you get left upper abdominal pain or pain at the tip of your shoulder;
- if you have an allergy to latex. The needle cover on the pre-filled syringe contains a derivative of latex and may cause severe allergic reactions.

### **Pregnancy and Breastfeeding**

NEULASTIM should not be administered during pregnancy and breast feeding.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking NEULASTIM.

### **Driving and Using Machinery**

The effect of NEULASTIM on the ability to drive or use machinery is not known.

### **Important information about some of the ingredients of NEULASTIM**

NEULASTIM contains sorbitol (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NEULASTIM. NEULASTIM is essentially sodium-free.

### **Taking other medicines with NEULASTIM**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)

### **HOW TO TAKE NEULASTIM**

Therapy with NEULASTIM should be initiated by medical practitioners experienced in the above-mentioned indications. As allergic reactions were observed in isolated cases, it is recommended that the first dose be administered under medical supervision.

Always use NEULASTIM exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Do not shake NEULASTIM vigorously as this may affect its activity.

### **Injecting NEULASTIM yourself**

Your doctor may decide that it would be more convenient for you to inject NEULASTIM yourself. Your doctor or nurse will show you how to inject yourself. Do not try to inject yourself if you have not been trained.

#### **If you use more NEULASTIM than you should:**

If you use more NEULASTIM than you should, contact your doctor, nurse or pharmacist.

#### **If you forget to take NEULASTIM:**

Do not take a double dose to make up for forgotten individual doses.

Do not share medicines prescribed for you with another person.

**In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.**

### **POSSIBLE SIDE EFFECTS**

NEULASTIM can have side effects. The following side effects and adverse events have been reported under NEULASTIM therapy.

A very common side effect is bone pain. Your doctor will tell you what you can take to ease the bone pain.

Common side effects include pain at the site of the injection, headaches, and general aches and pains in the joints, muscles, chest, limbs, neck or back. An uncommon side effect is nausea.

Allergic-type reactions to NEULASTIM, including redness and flushing, skin rash, raised areas of the skin that itch and anaphylaxis (weakness, drop in blood pressure, difficulty breathing, swelling of the face), have been reported.

Increased spleen size and rare cases of spleen rupture have been reported after the use of NEULASTIM.

Some cases of splenic rupture were fatal.

It is important that you contact your doctor immediately if you experience pain in the upper left side of the abdomen or left shoulder pain since this may relate to a problem with your spleen.

Rare cases of breathing problems have been reported after taking G-CSFs. If you have a cough, fever and difficulty in breathing please tell your doctor.

Some changes may occur in your blood, but these will be detected by routine blood tests. Your platelet count may become low. This may result in bruising. Your white blood cell count may become high for a short period of time.

Sweet's syndrome (plum-coloured, raised, painful lesions on the limbs and sometimes in the face and neck, with fever) has occurred rarely. Cutaneous vasculitis (inflammation of the blood vessels in the skin) has rarely occurred in patients receiving NEULASTIM.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Not all side effects reported for NEULASTIM are included in this leaflet. Should your general health worsen while taking this medicine, consult your doctor, pharmacist or other health care professional for advice.**

### **STORING AND DISPOSING OF NEULASTIM**

Store all medicines out of the reach and sight of children.

Store at 2 - 8 °C (in a refrigerator). Do not freeze.

Keep the container in the outer carton, in order to protect from light.

Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect the stability of NEULASTIM.

NEULASTIM may be exposed to room temperature (not above 30 °C) for a maximum single period of up to 72 hours. NEULASTIM left at room temperature for more than 72 hours should be discarded.

Do not use after the expiry date (EXP) shown on the pack.

Do not shake NEULASTIM vigorously as it may affect its activity. Do not use NEULASTIM if you notice any particles in it.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

### **PRESENTATION OF NEULASTIM**

NEULASTIM is packed 1 ml clear colourless Type I glass pre-filled syringe (containing 6 mg/0,6 ml) with a stainless-steel needle, for single use only. Cartons with 1 or 5 syringes.

### **IDENTIFICATION OF NEULASTIM**

NEULASTIM is a clear and colourless liquid, practically free from particles.

### **REGISTRATION NUMBER**

42/8.5/0592

### **NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER**

Amgen South Africa (Pty) Ltd.  
Building D, Ballyoaks Office Park, 35 Ballyclare Drive,  
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