Neustim®

Pegfilgrastim

Pegfilgrastim
6mg/ 0.6 ml
Sterile Pre- Filled Syringe

Pharmacological -Therapeutic Category:

Granulocyte-Colony Stimulating Factor-Hematopoietic Agent

Pharmacodynamics - Pharmacokinetic:

Pegfilgrastim stimulates the production, maturation, and activation of neutrophils, Pegfilgrastim activates neutrophils to increase both their migration and cytotoxicity. Pegfilgrastim has a prolonged duration of effect relative to filgrastim and a reduced renal clearance.
Neutrophil receptor binding is an important component of the clearance of Pegfilgrastim, and serum clearance is directly related to the number of neutrophils. In addition to numbers of neutrophils, body weight appeared to be a factor. Patients with higher body weights experienced higher systemic exposure to Pegfilgrastim after receiving a dose normalized for body weight. A large variability in the pharmacokinetics of Pegfilgrastim was observed.
The half-life of Neustim® ranged from 15 to 80 hours after subcutaneous injection.
No gender-related differences were observed in the pharmacokinetics of Pegfilgrastim, and no differences were observed in the pharmacokinetics of geriatric patients (≥65 years of age) compared with younger patients (< 65 years of age). Renal dysfunction had no effect on the pharmacokinetics of Pegfilgrastim. No dosage adjustment is necessary. The pharmacokinetic profile in patients with hepatic insufficiency has not been assessed.

Indications:

To decrease the incidence of infection, by stimulation of granulocyte production, in patients with non-myeloid malignancies receiving myelosuppressive therapy associated with a significant risk of febrile neutropenia

Dosage and Administration:

Adult:
Prevention of chemotherapy-induced neutropenia:
6 mg SC once per chemotherapy cycle, beginning 24-72 hours after completion of chemotherapy.
For patients acutely exposed to myelosuppressive doses of radiation, two doses, 6 mg each, administered subcutaneously one week apart. Administer the first dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation, and a second dose one week after.

Geriatric:
Refer to adult dosing

Contraindications:

Hypersensitivity to Pegfilgrastim, filgrastim or any component of the formulation.

Precaution/ Warning:

Keep this medicine out of the sight and reach of children.
This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms of illness are the same as yours.
Talk to your doctor, pharmacist or nurse before using Neustim® if you:

- Experience an allergic reaction including weakness, drop in blood pressure, difficulty breathing, swelling of the face, redness and flushing, skin rash and areas of the skin that itch
- Have an allergy to latex. The needle cap on the pre-filled syringe contains a derivative of latex and may cause severe allergic reactions
- Experience a cough, fever and difficulty breathing. This can be a sign of Acute Respiratory Distress Syndrome (ARDS)
- Have any of the following or combination of the following side effects:
  Swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness. These could be symptoms of condition called "Capillary Leak Syndrome".
- Get left upper abdominal pain or pain at the tip of your shoulder. This may be a sign of a problem with your spleen (splenomegaly).
- Have recently had a serious lung infection (pneumonia), fluid in the lungs (pulmonary edema), inflammation of the lungs (interstitial lung disease) or an abnormal chest x-ray (lung infiltration).
- Are aware of any altered blood cell counts (e.g. increase in white blood cells or anemia) or decreased blood platelet counts, which reduces the ability of your blood to clot (thrombocytopenia). Your doctor may want to monitor you more closely.
- Have sickle cell anemia. Your doctor may monitor your condition more closely.
- Have sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. These could be signs of a severe allergic reaction.

Your doctor will check your blood and urine regularly as Neustim® can harm the tiny filters inside your kidneys (glomerulonephritis).

Pregnancy Risk Factor: C

Lactation:

Excretion in breast milk is unknown.

Loss of response to Pegfilgrastim

If you experience a loss of response or failure to maintain a response with Pegfilgrastim treatment, your doctor will investigate the reasons why including whether you have developed antibodies which neutralize Pegfilgrastim's activity.

Drug Interactions

No formal drug interaction studies between Neustim® and other drugs have been performed.
Increased hematopoietic activity of the bone marrow in response to growth factor therapy may result in transiently positive bone-imaging changes. Consider these findings when interpreting bone-imaging results.
Neustim® contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects (or adverse reactions):

Peripheral edema, headache, vomiting, bone pain, myalgia, arthralgia, weakness, constipation. Important or life-threatening adverse reactions: Acute respiratory distress syndrome (ARDS), allergic reaction, anaphylaxis, cutaneous vasculitis, erythema, fever, flushing, hyper leukocytosis, hypoxia, injection site reactions (erythema, induration, pain), leukocytosis, rash, sickle cell crisis, splenic rupture, Sweet's syndrome (acute febrile dermatosis), urticaria. cytopenia resulting from an antibody response to exogenous growth factors have been reported on rare occasions in patients treated with other recombinant growth factors.

Storage:

Store between 2-8 °C (in refrigerator) in the carton to protect from light and do not freeze.
Do not shake.
Discard syringes stored at room temperature for more than 48 hours.

How to use Neustim®

It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
Neustim® is given as an injection into the tissue just under the skin (subcutaneous injection).
If you use more Neustim® than you should, contact your doctor or pharmacist.
If you forget to inject Neustim® you should contact your doctor to discuss when you should inject the next dose.

What Neustim® contains:

Pegfilgrastim is the active substance of this medicinal product. Each pre-filled syringe contains Pegfilgrastim with the concentration of 6 mg/ 0.6 mL.
Other ingredients are D-Sorbitol, Polysorbate 20, Sodium acetate Trihydrate, water for injections (WFI).

Packaging:

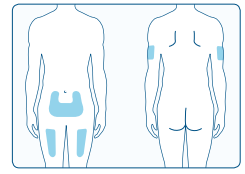
Neustim® is available in pack containing 1 sterile pre-filled syringe and PIL.

Setting up for an injection

1. Select a clean, well-lit, flat working surface, such as a table.
2. Take the Neustim® carton containing the pre-filled syringe out of the refrigerator and place it on your flat working surface. Remove one prefilled syringe and place it on your working surface. Do NOT shake the pre-filled syringe of Neustim®.
3. Check the expiration date on the pre-filled syringe. Do NOT use this medicine after the expiry date.
4. Do NOT use the pre-filled syringe if the needle cover is missing or not securely attached.
5. For a more comfortable injection, allow the Neustim® in the pre-filled syringe to reach room temperature (approximately 15 to 30 minutes). Do NOT remove the needle cover while allowing it to reach room temperature. Do NOT warm Neustim® in any other way (for example, do NOT warm it in a microwave oven or in hot water).
6. Assemble the additional supplies you will need for your injection.
7. Wash your hands thoroughly with soap and warm water.
8. Make sure the solution in the pre-filled syringe is clear, colorless or slightly yellow. Do NOT inject the solution if it is cloudy or discolored, or contains visible or colored particles or if the pre-filled syringe appears cracked or broken.
9. Do not throw away any medicines via waste water or household waste.

Choosing and Preparing an Injection Site

1. Three recommended injection sites for Neustim® using a pre-filled syringe include:
   a. Upper part of your thigh.
   b. Belly, except for a 5 cm (2-inch) area right around your belly button.
   c. Outer area of upper arm (only if someone else is giving you the injection).

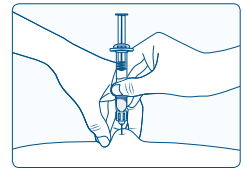


2. Rotate the site for each injection. Make sure that the new injection is given at least one inch from sites of recent injections. Do NOT inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks. Do NOT inject into vein or into a muscle.
3. To prepare the area of skin where Neustim® is to be injected, wipe the injection site with an alcohol swab. Do NOT touch this area again before giving the injection.

Injecting Neustim® Using a Pre-filled Syringe

Do NOT remove the needle cover from the pre-filled syringe until you are ready to inject.

1. Pick up the pre-filled syringe from your flat working surface. Hold the barrel of the pre-filled syringe with one hand and pull the needle cover straight off. To avoid damaging the needle, do NOT twist or bend the needle cover while you are removing it, and do NOT try to put the needle cover back onto the pre-filled syringe. When you remove the needle cover, there may be a drop of liquid at the end of the needle; this is normal. Do NOT touch the needle or allow it to touch any surface. Do NOT touch or bump the plunger. Doing so could cause the liquid to leak out.
2. Hold the syringe in one hand like a pencil, use the other hand to gently pinch a fold of skin at the cleaned injection site and hold it firmly.



3. Insert the needle at a slight angle (90 degree) to the skin. After the needle is inserted, let go of the skin. Slowly push the plunger all the way down to injects Neustim®.
4. When the syringe is empty, remove the needle from the skin, being careful to keep it at the same angle it was when it was inserted.
5. Press the alcohol swab over the injection site for 10 seconds. If you have severe bleeding cover the injection site with a bandage.

Disposing of Supplies

1. The syringe should NEVER be reused.
2. Follow any special provincial or local laws regarding the proper disposal of needles and syringes.
3. Used alcohol swabs should be placed in the trash.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Manufactured by
SINGAPORE BIOTECH