Patient Information Leaflet for PEGYLASTIN

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PEGYLASTIN injection

Read all of this leaflet carefully before you start receiving PEGYLASTIN.

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

1. WHAT PEGYLASTIN CONTAINS:

Each pre-filled syringe or pre-filled injector contains 6 mg pegfilgrastim in 0,6 mL (10 mg/mL) solution for injection.

Pegfilgrastim is composed of filgrastim (recombinant methionyl human granulocyte colony-stimulating factor (G-CSF)) with a 20 kDa polyethylene glycol (PEG) molecule covalently bound to the N-terminal methionine residue.

Inactive ingredients: Polysorbate 20, sorbitol and water for injection.

Contains sugar (30 mg sorbitol per 0,6 mL).

2. WHAT PEGYLASTIN IS USED FOR:

PEGYLASTIN contains the active ingredient pegfilgrastim. Pegfilgrastim is a protein produced using biotechnology in bacteria called *Escherichia coli*. 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.

PEGYLASTIN 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 the number of 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 PEGYLASTIN to encourage your bone marrow (part of the bone which makes blood cells) to produce more white blood cells that help your body fight infection.

3. BEFORE YOU RECEIVE PEGYLASTIN:

You should not be given PEGYLASTIN:

If you are hypersensitive (allergic) to pegfilgrastim, filgrastim, *Escherichia coli*-derived proteins or to any of the inactive ingredients of PEGYLASTIN (see WHAT PEGYLASTIN CONTAINS).

Take special care with PEGYLASTIN:

- If you experience an allergic reaction including weakness, decreased blood pressure (dizziness or light-headedness), difficulty breathing, swelling of the face, redness and flushing, skin rash and areas of the skin that itch.
- If you experience pain in your upper left abdominal area or pain at the tip of your shoulder. This may be a sign of a problem with your spleen (splenomegaly).
- If you have sickle cell anaemia (a disease in which your body produces abnormally shaped red blood cells). Your doctor may monitor your condition more closely.
- If you are aware of any altered blood cell counts (e.g. increase or decrease in white blood cells) or decreased blood platelet counts, which reduces the ability of your blood to clot (thrombocytopenia). Your doctor may want to monitor you more closely.
- If you have recently had a serious lung infection (pneumonia), fluid in the lungs (pulmonary oedema), inflammation of the lungs (interstitial lung disease) or an abnormal chest X-ray (lung infiltration).

- If you have any of the following or combination of the following symptoms:
  - dizziness or light-headedness,
  - swelling or puffiness, which may be associated with passing water less frequently,
  - difficulty breathing, swelling in your stomach area and feeling of fullness, and a general feeling of tiredness.

  These could be symptoms of a condition called capillary leak syndrome which causes blood to leak from the small blood vessels into your body.

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

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before receiving PEGYLASTIN.

Driving and using machinery:

PEGYLASTIN has no or negligible effect on the ability to drive a vehicle or use machines. However, take special care before performing tasks requiring your attention, until you know you will react to PEGYLASTIN.

Taking other medicines with PEGYLASTIN:

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

PEGYLASTIN may have an interaction with 5-fluorouracil (5-FU) (used to treat cancer).

4. HOW TO RECEIVE PEGYLASTIN:

PEGYLASTIN will be administered by a healthcare provider experienced in the treatment of cancer, in a hospital setting.

PEGYLASTIN is for single use only.

The usual dose is one 6 mg injection under your skin (subcutaneous) at least 24 hours after your last dose of chemotherapy at the end of each chemotherapy cycle.

PEGYLASTIN is not intended for use in children and adolescents under the age of 18 years.

If you receive more PEGYLASTIN than you should:

PEGYLASTIN will be administered by your doctor. He/she will monitor for and treat any symptoms if an overdose occurs.

If you missed a dose of PEGYLASTIN:

PEGYLASTIN is administered under the supervision of your doctor. If you think that you may have missed a dose, talk to your doctor or healthcare provider.

5. POSSIBLE SIDE EFFECTS

PEGYLASTIN can have side effects.

Not all side effects reported for PEGYLASTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PEGYLASTIN, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all serious side effects. If you have them, you may have had a serious allergic reaction to PEGYLASTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Occurring less frequently:

- severe respiratory problems (characterised by shortness of breath, dizziness, light-headedness, unusually fast breathing, confusion, exhaustion, blue-tinted lips or nails)
- swelling or puffiness (which may be associated with passing water less frequently), difficulty breathing, swelling in the stomach area, feeling of fullness, general feeling of tiredness. These symptoms could be of a condition called “capillary leak syndrome”, which develop rapidly and causes blood to leak from the small blood vessels into your body.

These are all serious side effects. You may need urgent medical attention.

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

Occurring frequently:

- blood disorders (increased number of white blood cells, or bleeding or bruising more easily than usual)
- headache
- feeling sick (nausea)
- pain in the bones, joints, muscles, back, limbs or neck
- painful or difficult urination
- pain or redness at the site of injection, chest pain (non-cardiac), general pain.

Occurring less frequently:

- sickle cell crisis (characterised by unusual weakness or tiredness, pain, swelling and inflammation of the hands, feet and/or joints)
- increased spleen size, which may lead to spleen rupture (characterised by pain or fullness in the left upper stomach area that may spread to the left shoulder), anaemia (a blood disorder, characterised by tiredness, headaches, shortness of breath, dizziness and paleness)
- low levels of potassium (characterised by constipation, unusual weakness, muscle spasms)

- gout (swelling and pain in the ankles, knees, feet, wrists or elbows)
- nose bleeds, cutaneous vasculitis (inflammation of the blood vessels in the skin)
- breathing problems (associated by a cough, fever and difficulty breathing)
- gastrointestinal disorders (heartburn, nausea, vomiting or bloating)
- glomerulonephritis (a kidney problem characterised by pink coloured or foamy urine, frequent night-time urination, high blood pressure, swelling of your ankles and face).

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

6. STORING AND DISPOSING OF PEGYLASTIN

Store at 2 – 8 °C (in a refrigerator).

Do not freeze.

Keep pre-filled syringe in outer carton to protect from light.

PEGYLASTIN may be exposed to room temperature (at or below 25 °C) for a maximum single period of up to 15 days. PEGYLASTIN left at room temperature for more than 15 days should be discarded.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF PEGYLASTIN

PEGYLASTIN presents either as a pre-filled syringe or a pre-filled injector.

Pre-filled syringe: 1 mL clear, colourless, Type I borosilicate glass, pre-filled syringe with a permanently attached stainless steel injection needle, with a needle safety guard. The needle cover of the pre-filled syringe contains dry natural rubber.

Each pre-filled syringe contains 0,6 mL of solution for injection. Pack size of one pre-filled syringe with one alcohol swab, in a blistered packaging.

Pre-filled injector: 1 mL clear, colourless, Type I borosilicate glass, pre-filled syringe with a permanently attached stainless steel injection needle. The pre-filled syringe is externally equipped with the device for self-administration (pre-filled injector). The needle cover of the pre-filled syringe contains dry natural rubber.

Each pre-filled syringe injector contains 0,6 mL of solution for injection. Pack size of one pre-filled injector with one alcohol swab, in a blistered packaging.

For single use only. One pre-filled syringe or pre-filled injector is packed in an outer carton.

8. IDENTIFICATION OF PEGYLASTIN

Clear and colourless liquid, free from visible particles.

9. REGISTRATION NUMBER

53/8.5/0329

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Accord Healthcare (Pty) Ltd.

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11. DATE OF PUBLICATION

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