PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

STROPEG 6 mg/0,6 ml solution for injection

Pegfilgrastim

Contains sugar: D-sorbitol

Read all of this leaflet carefully before you are given STROPEG

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- STROPEG 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 is in this leaflet

1. What STROPEG is and what it is used for
2. What you need to know before you receive STROPEG
3. How to use STROPEG
4. Possible side effects
5. How to store STROPEG
6. Contents of the pack and other information

1. What STROPEG is and what it is used for

STROPEG 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.

STROPEG 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 STROPEG 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.

2. What you need to know before you receive STROPEG

STROPEG should not be administered to you:

- If you are hypersensitive (allergic) to pegfilgrastim, filgrastim, *E. coli* derived proteins, or any of the other ingredients of STROPEG (listed in section 6).

Warnings and precautions

Take special care with STROPEG:

- if you experience an allergic reaction including weakness, drop in blood pressure, difficulty breathing, swelling of the face (anaphylaxis), redness and flushing, skin rash and areas of the skin that itch.

- if you experience a cough, fever and difficulty breathing. This can be a sign of Acute Respiratory Distress Syndrome (ARDS).
- if you 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 a condition called “Capillary Leak Syndrome” which causes blood to leak from the small blood vessels into your body. See section 4.
- if you 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).
- 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 are aware of any altered blood cell counts (e.g. increase in white blood cells or anaemia) 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 sickle cell anaemia. Your doctor may monitor your condition more closely.
- if you 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.

Inflammation of aorta (the large blood vessel which transports blood from the heart to the body) has been reported less frequently in cancer patients and healthy donors. The symptoms can include fever, abdominal pain, malaise, back pain and increased inflammatory markers. Tell your doctor if you experience those symptoms.

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

Severe skin reactions (Stevens-Johnson syndrome) have been reported with the use of STROPEG. Stop using STROPEG and seek medical attention immediately if you notice any of the symptoms described in section 4.

You should talk to your doctor about your risks of developing cancers of the blood. If you develop or are likely to develop cancers of the blood, you should not use STROPEG, unless instructed by your doctor.

Loss of response to STROPEG

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

Children and adolescents

STROPEG is for use in adults aged 18 and over.

Other medicines and STROPEG

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

STROPEG should not be administered during pregnancy and breast feeding.

Driving and using machines

STROPEG has no or negligible effect on the ability to drive or use machines.

STROPEG contains D-sorbitol

STROPEG contains D-sorbitol. If you have been told that you have an intolerance to some sugars, you should not use STROPEG.

3. How to use STROPEG

Do not share medicines prescribed for you with any other person.

Therapy with STROPEG 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 STROPEG exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

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

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

Injecting STROPEG yourself

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

Your doctor will tell you how long your treatment with STROPEG will last. If you have the impression that the effect of STROPEG is too strong or too weak, tell your doctor or pharmacist.

If you inject more STROPEG than you should

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

If you forget to inject STROPEG

If you are injecting yourself and have forgotten your dose of STROPEG, you should contact your doctor to discuss when you should inject the next dose.

4. Possible side effects

STROPEG can have side effects.

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

If any of the following happens, stop receiving STROPEG and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to STROPEG. 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:

- 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 symptoms generally develop in a rapid fashion. These could be symptoms of n less frequent condition called “Capillary Leak Syndrome” which 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 if you notice any of the following:

Frequent

- bone pain,
- nausea and headaches,
- rash, itchy red raised bumps (contact dermatitis/local skin reactions),
- pain at the site of injection,
- application site reactions which may include redness, bleeding, bruising, pain and discomfort,
- general aches and pains in the joints and muscles,
- some changes may occur in your blood, but these will be detected by routine blood tests. Your white blood cell count may become high for a short period of time. Your platelet count may become low which might result in bruising.

Less frequent

- allergic-type reactions, including redness and flushing, skin rash, and raised areas of the skin that itch,
- serious allergic reactions, including anaphylaxis (weakness, drop in blood pressure, difficulty breathing, swelling of the face),
- increased spleen size,
- spleen rupture. 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.

- breathing problems (cough, fever and difficulty breathing),
- Sweet's syndrome (plum-coloured, raised, painful lesions on the limbs and sometimes the face and neck with fever),
- cutaneous vasculitis (inflammation of the blood vessels in the skin),
- damage to the tiny filters inside your kidneys (glomerulonephritis),
- redness at the site of injection,
- coughing up blood (haemoptysis),
- inflammation of aorta (the large blood vessel which transports blood from the heart to the body), see section 2,
- bleeding from the lung (pulmonary haemorrhage),
- Stevens-Johnson syndrome, which can appear as reddish target-like or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using STROPEG if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of STROPEG.

5. How to store STROPEG

Store all medicines out of reach of children.

- Store at 2 – 8 ˚C (in a refrigerator).
- Do not freeze or shake.
- 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 48 hours does not adversely affect the stability of STROPEG.
- STROPEG may be exposed to room temperature (not above 30 ˚C) for a maximum single period of up to 72 hours. STROPEG left at room temperature for more than 72 hours should be discarded.
- Do not use after the expiry date stated on the label / carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What STROPEG contains

- STROPEG pre-filled syringes contain the active ingredient, pegfilgrastim. Each pre-filled syringe contains 6 mg pegfilgrastim in 0,6 ml solution. Contains sugar: D-sorbitol 30 mg per pre-filled syringe.
- The other ingredients are: D-sorbitol (E420), glacial acetic acid, polysorbate 20, sodium hydroxide and water for injection.

What STROPEG looks like and contents of the pack

STROPEG is a clear, colourless solution free from visible particles.

STROPEG is packed in 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 contain one single-use, pre-filled syringe along with a patient information leaflet.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

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This leaflet was last revised in

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Registration number

560108

Access to the corresponding Professional Information

To be confirmed.