PATIENT INFORMATION LEALTET

SCHEDULING STATUS: **S4**

FILGRASTIM TEVA 30, 30 MIU/0,5 mL solution for injection or infusion

FILGRASTIM TEVA 48, 48 MIU/0,8 mL solution for injection or infusion

Filgrastim

Contains sugar (Each mL of solution contains 50 mg of sorbitol)

Read all of this leaflet carefully before you start using FILGRASTIM TEVA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FILGRASTIM TEVA 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 FILGRASTIM TEVA is and what it is used for

FILGRASTIM TEVA contains filgrastim, a white blood cell growth factor (granulocyte colony stimulating factor [G- CSF]). FILGRASTIM TEVA works by stimulating the bone marrow (the tissue where new blood cells are made) to produce more white blood cells. White blood cells are important as they help your body fight infection.

FILGRASTIM TEVA is used to increase the number of white blood cells after treatment with to help prevent infections.

2. What you need to know before you use FILGRASTIM TEVA

Do not use FILGRASTIM TEVA:

- If you are hypersensitive (allergic) to filgrastim or any of the other ingredients of FILGRASTIM TEVA (listed in section 6).
- If you have severely low white blood cell levels that were detected soon after your birth (Kostmann's syndrome) with abnormal cell structure or function.
- If you have kidney or liver problems.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection if:

Special care should be taken with FILGRASTIM TEVA:

- You have a history sickle cell disease, because FILGRASTIM TEVA can cause sickle cell crisis (a painful episode that occurs in people who have sickle cell anaemia. Sickle shaped red blood cells block blood vessels. Blood and oxygen cannot get to the tissues, causing pain).
- If you have osteoporosis (bone disease). Your doctor will monitor your bone mineral density if you are receiving FILGRASTIM TEVA for more than 6 months.

- If you have symptoms of cough, fever, shortness of breath or trouble breathing because these may be signs of a serious lung problem called Acute Respiratory Distress Syndrome (ARDS). Stop treatment with FILGRASTIM TEVA immediately and consult your doctor if you have any of these symptoms (see Possible side effects).

Other medicines and FILGRASTIM TEVA

Always tell your healthcare 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 healthcare provider for advice before using FILGRASTIM TEVA.

FILGRASTIM TEVA has not been tested in pregnant women.

You should not be given FILGRASTIM TEVA if you are pregnant or breastfeeding.

It is unknown whether FILGRASTIM TEVA passes into the breast milk. You should not use FILGRASTIM TEVA if you are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent FILGRASTIM TEVA may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which FILGRASTIM TEVA affects you.

If you experience fatigue (extreme tiredness), do not drive or use any tools or machines.

FILGRASTIM TEVA contains sorbitol

FILGRASTIM TEVA contains 50 mg sorbitol in each mL (a type of sugar).

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects. You must tell your doctor before receiving FILGRASTIM TEVA if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

3. How to use FILGRASTIM TEVA

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

Always use FILGRASTIM TEVA exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose:

FILGRASTIM TEVA is usually given as a daily injection into the tissue just under the skin (known as a subcutaneous injection). It can also be given as a daily slow injection into the vein (known as an intravenous infusion). The dosage will vary depending on your illness and weight.

Your doctor will tell you how much FILGRASTIM TEVA you will be administered.

You will be given FILGRASTIM TEVA until your white blood cell count is normal.

Regular blood tests will be taken to monitor the number of white blood cells in your body.

If you have the impression that the effect of FILGRASTIM TEVA is too strong or too weak, tell your doctor or pharmacist. It is quite normal to have a number of courses of FILGRASTIM TEVA treatment.

The usual dose is 0,5 million international units (MIU) per kilogram of body weight each day.

Your treatment will usually last for about 14 days. In some disease types however, longer treatment lasting up to one month may be required.

Method of administration:

If you are receiving this medicine by subcutaneous injection, your doctor may suggest that you learn how to give yourself the injection. Your doctor or nurse will give you instructions on how to do this. Do not attempt to self-administer without this training. Some of the information you require is given at the end of this package leaflet, but proper treatment of your disease requires close and constant co-operation with your doctor.

Keep all your appointments for your FILGRASTIM TEVA injections and blood tests.

Each pre-filled syringe is for single use only.

If you use more FILGRASTIM TEVA 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 use FILGRASTIM TEVA

Do not use a double dose to make up for a forgotten injection.

If you stop using FILGRASTIM TEVA

Before you stop using FILGRASTIM TEVA, talk to your doctor.

4. Possible Side effects

FILGRASTIM TEVA can have side effects.

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

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

- Weakness, drop in blood pressure, difficulty breathing, swelling of the face (anaphylaxis).
- Skin rash, itchy rash (urticarial).
- Swelling of the face, lips, mouth, tongue or throat (angioedema).
- Shortness of breath (dyspnoea).

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

- Cough, fever and difficulty breathing as this can be a sign of Acute Respiratory Distress Syndrome (ARDS).
- Severe pain in the bones, chest, gut or joints (sickle cell crisis).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea (feeling sick).
- Vomiting.
- Constipation.

- Diarrhoea.
- Lack of appetite (anorexia).
- Headache.
- Sore throat.
- Extreme tiredness (fatigue), general weakness.
- Hair loss.
- Chest pain.
- Musculoskeletal pain.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Any of the following or combination of the following adverse 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 an uncommon condition called ‘Capillary Leak Syndrome’, which causes blood to leak from the small blood vessels into your body and needs urgent medical attention.

- Vascular disorder (a disorder that affects the blood vessels)
- Pseudogout (a form of arthritis that causes pain, stiffness, tenderness, redness, warmth, and swelling in some joints).
- Abnormal X-rays of the lung (Pulmonary infiltrates).
- Inflammation of the blood vessels in the skin (cutaneous vasculitis).
- Sweets syndrome (plum-coloured, raised, painful sores on the limbs and sometimes the face and neck with a fever).
- Worsening of rheumatoid arthritis.
- Painful or difficult urination or urinary problems.

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 the "**6.04 Adverse Drug Reaction 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 FILGASTRIM TEVA.

5. How to store FILGRASTIM TEVA

Store between 2 °C – 8 °C in a refrigerator.

Within its shelf-life and for ambulatory use, the product may be removed from the refrigerator (2 °C – 8 °C) and stored at a temperature up to 25 °C for one single period of up to 4 days. If not used within 4 days, the product may be returned to the refrigerator (2 °C – 8 °C) up to the expiry date. Dispose of syringes if stored above 8 °C for more than 4 days.

Store all medicines out of reach of children.

Do not use FILGRASTIM TEVA after the expiry date which is stated on the outer carton and on the pre-filled syringe. The expiry date refers to the last day of that month.

Do not use FILGRASTIM TEVA if you notice it is cloudy or there are particles in it. Each pre-filled syringe is for single use only. Accidental exposure to freezing temperatures does not adversely affect the stability of FILGRASTIM TEVA.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What FILGRASTIM TEVA contains

The active substance is filgrastim. Each mL of solution for injection or infusion contains 60 million international units [MIU] (600 µg) of filgrastim.

FILGRASTIM TEVA 30: Each pre-filled syringe contains 30 MIU (300 µg) of filgrastim in 0,5 mL solution or infusion.

FILGRASTIM TEVA 48: Each pre-filled syringe contains 48 MIU (480 µg) of filgrastim in 0,8 mL solution or infusion.

The other ingredients are acetic acid glacial, polysorbate 80 and water for injections. Each mL of solution contains 50 mg of sorbitol.

What FILGRASTIM TEVA looks like and contents of the pack

FILGRASTIM TEVA is a clear colourless solution, practically free from particles.

Diluted solution: Clear, colourless solution free from visible particulate matter.

FILGRASTIM TEVA 30 is available in Type I clear colourless glass pre-filled syringes with a green polypropylene plunger rod and grey bromobutyl rubber plunger stopper, with a permanently attached stainless steel needle with or without a colourless safety device to prevent needle stick injury and re-use.

Available in cardboard carton packs containing 1, 5 or 10 pre-filled syringes with 0,5 mL solution; or Multipacks containing 10 (2 packs of 5) pre-filled syringes with 0,5 mL solution.

FILGRASTIM TEVA 48 is available in Type I clear colourless glass pre-filled syringes with a blue polypropylene plunger rod and grey bromobutyl rubber plunger stopper, with a permanently attached stainless steel needle with or without a colourless safety device to prevent needle stick injury and re-use.

Available in cardboard carton packs containing 1, 5 or 10 pre-filled syringes with 0,8 mL solution;

or Multipacks containing 10 (2 packs of 5) pre-filled syringes with 0,8 mL solution.

The syringes with safety device will be packaged inside the cartons either as paper-backed thermoformed PVC blisters or in plastic trays divided into wells, with one syringe per blister or well.

Syringes without safety device will be packaged into cardboard boxes with cardboard trays.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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To be allocated

Registration number

FILGRASTIM TEVA 30: 46/32.16/0317

FILGRASTIM TEVA 48: 46/32.16/0318

INFORMATION FOR INJECTING YOURSELF

This section contains information on how to give yourself an injection of FILGRASTIM TEVA. It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. If you are not sure about giving yourself the injection or you have any questions, please ask your doctor or nurse for help.

FILGRASTIM TEVA is supplied in pre-filled syringes either with or without safety device. The figures below refer either to syringes with safety device (figures 2a, 2b, 7 and 8) or without (figures 1a and 1b). The other figures (3, 4, 5, 6) apply to both syringes. Your doctor or pharmacist can tell you which pre-filled syringe you have received. It is important that you dispose of the syringe without safety device in a puncture-proof container.

How do I inject FILGRASTIM TEVA myself?

You will need to give yourself the injection into the tissue just under the skin. This is known as a subcutaneous injection. You will need to have your injections at about the same time every day.

Equipment that you need

To give yourself a subcutaneous injection you will need:

- a pre-filled syringe of FILGRASTIM TEVA,
- alcohol wipes or similar,
- a puncture-proof container (plastic container provided by the hospital or pharmacy) so you can dispose of used syringes without safety device safely.

What should I do before I give myself a subcutaneous injection of FILGRASTIM TEVA?

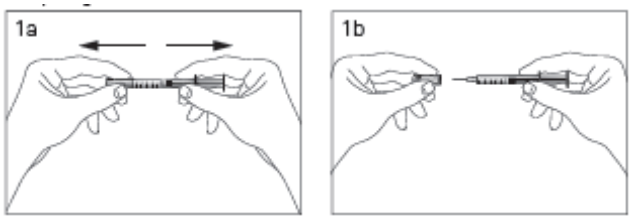
1. Try to self-inject at approximately the same time every day.
2. Take your FILGRASTIM TEVA pre-filled syringe out of the refrigerator.
3. Check the expiry date on the pre-filled syringe label (EXP). Do not use it if the date has passed the last day of the month shown.
4. Check the appearance of FILGRASTIM TEVA. It must be a clear and colourless liquid. If there are particles in it, you must not use it.
5. For a more comfortable injection, let the pre-filled syringe stand for 30 minutes to reach room temperature or hold the pre-filled syringe gently in your hand for a few minutes. Do not warm FILGRASTIM TEVA in any other way (for example, do not warm it in a microwave or in hot water).
6. Do not remove the cover from the syringe until you are ready to inject.
7. Wash your hands thoroughly.
8. Find a comfortable, well-lit place and put everything you need where you can reach them (the FILGRASTIM TEVA pre-filled syringe, alcohol wipes and the puncture-proof container).

How do I prepare my FILGRASTIM TEVA injection?

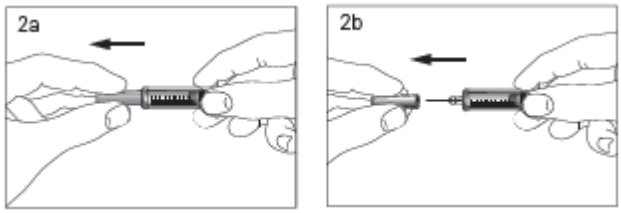
Before you inject FILGRASTIM TEVA you must do the following:

1. Hold the syringe and gently take the cover from the needle without twisting. Pull straight as shown in pictures 1 and 2 (see pictures 1a and 1b for syringes without safety device and pictures 2a and 2b for syringes with safety device). Do not touch the needle or push the plunger.

   Without safety device



With safety device

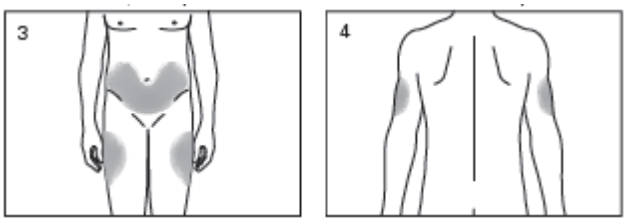


2. You may notice a small air bubble in the pre-filled syringe. If there are air bubbles present, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. With the syringe pointing upwards, expel all air from the syringe by pushing the plunger upwards.
3. The syringe has a scale on the syringe barrel. Push the plunger up to the number (mL) on the syringe that matches the dose of FILGRASTIM TEVA that your doctor prescribed.
4. Check again to make sure the correct dose of FILGRASTIM TEVA is in the syringe.
5. You can now use the pre-filled syringe.

Where should I give my injection?

The most suitable places to inject yourself are:

- the top of your thighs; and
- the abdomen, except for the area around the navel (see picture 3).



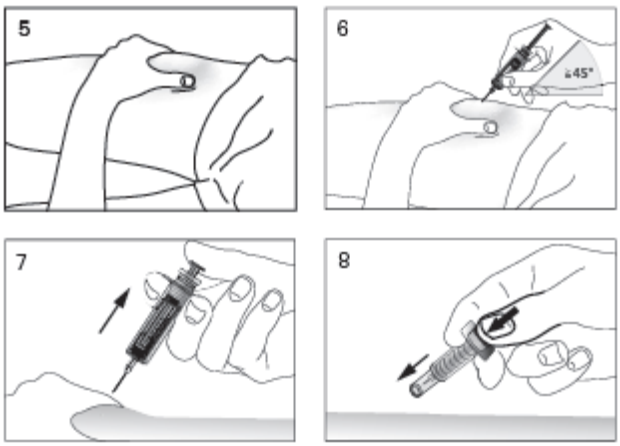
If someone else is injecting you, they can also use the back of your arms (see picture 4).

It is better to change the injection site every day to avoid the risk of soreness at any one site.

How do I give my injection?

1. Disinfect the injection site by using an alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it (see picture 5).
2. Put the needle fully into the skin as shown by your nurse or doctor (see picture 6).
3. Pull slightly on the plunger to check that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and re-insert it in another place.
4. Inject the liquid slowly and evenly, always keeping your skin pinched.
5. Inject only the dose your doctor has told you.
6. Syringe without safety device: After injecting the liquid, remove the needle and let go of your skin.

   Syringe with safety device: Remove the syringe from the injection site while keeping your finger on the plunger (see picture 7). Direct the needle away from you and others and activate the safety device by firmly pushing the plunger (see picture 8). You will hear a “click”, which confirms activation of the safety device. The needle will be covered by the protective sleeve so that you cannot prick yourself.
7. Only use each syringe for one injection. Do not use any FILGRASTIM TEVA that is left in the syringe.



With safety device

Remember

If you have any problems, please do not be afraid to ask your doctor or nurse for help and advice.

Disposing of used syringes

Syringes without safety device:

- Do not put the cover back on used needles.
- Put used syringes into the puncture-proof container and keep this container out of the reach and sight of children.
- Dispose of the full puncture-proof container as instructed by your doctor, nurse or pharmacist.
- Never put the syringes that you have used into your normal household rubbish bin.

Syringes with safety device:

- The safety device prevents needle stick injuries after use, so no special precautions for disposal are required. Dispose of syringes with safety device as instructed by your doctor, nurse or pharmacist.

THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY

FILGRASTIM TEVA does not contain any preservative. In view of the possible risk of microbial contamination, FILGRASTIM TEVA syringes are for single use only.

Accidental exposure to freezing temperatures does not adversely affect the stability of FILGRASTIM TEVA.

FILGRASTIM TEVA should not be diluted with sodium chloride solution. This medicine must not be mixed with other medicines except those mentioned below. Diluted filgrastim may be adsorbed to glass and plastic materials except diluted, as mentioned below.

If required, FILGRASTIM TEVA may be diluted in glucose 50 mg/mL (5 %) solution for infusion. Dilution to a final concentration less than 0,2 MIU (2 µg) per mL is not recommended at any time. The solution should be visually inspected prior to use. Only clear solutions without particles should be used. For patients treated with filgrastim diluted to concentrations below 1,5 MIU (15 µg) per mL, human serum albumin (HSA) should be added to a final concentration of 2 mg/mL. Example: In a final injection volume of 20 mL, total doses of filgrastim less than 30 MIU (300 µg) should be given with 0,2 mL of 200 mg/mL (20 %) human albumin solution added. When diluted in glucose 50 mg/mL (5 %) solution for infusion, FILGRASTIM TEVA is compatible with glass and a variety of plastics including PVC, polyolefin (a co-polymer of polypropylene and polyethylene) and polypropylene.

After dilution: Chemical and physical in-use stability of the diluted solution for infusion has been demonstrated for 24 hours at 2 °C to 8 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C.