PATIENT INFORMATION LEAFLET

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FILGRASTIM TEVA

3. HOW TO USE FILGRASTIM TEVA

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE FILGRASTIM TEVA

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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 chemotherapy 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**).

A precancerous condition called myelodysplastic syndrome (MDS) or a type of blood cancer called acute myeloid leukaemia (AML) have been reported with pegfilgrastim, a medicine like FILGRASTIM TEVA, when used in combination with chemotherapy and/or radiotherapy in breast and lung cancer patients. Although these conditions have not yet been reported with FILGRASTIM TEVA, your doctor

will monitor you for signs and symptoms of MDS/AML, which may include tiredness, fever, and easy bruising or bleeding.

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 to 8 °C in a refrigerator.

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:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park,

Magwa Crescent West

Waterfall City

Midrand

Gauteng

South Africa

2090

Tel No: (011) 055 0200

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Registration number(s):

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?

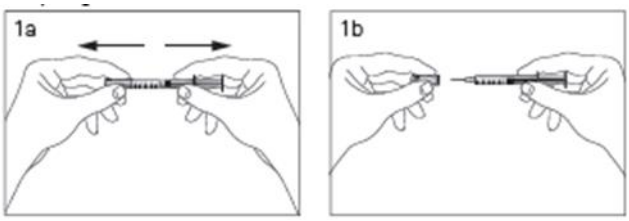
1. Try to self-inject at approximately the same time every day.
2. Take your FILGRASTIM TEVA pre-filled syringe out of the refrigerator.
3. Check the expiry date on the pre-filled syringe label (EXP). Do not use it if the date has passed the last day of the month shown.
4. Check the appearance of FILGRASTIM 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?

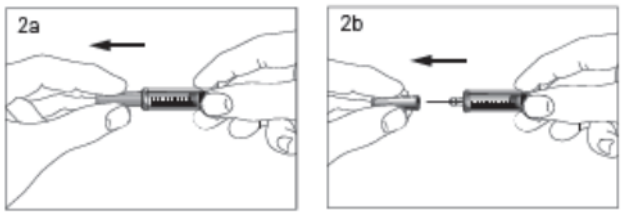
Before you inject FILGRASTIM TEVA you must do the following:

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:

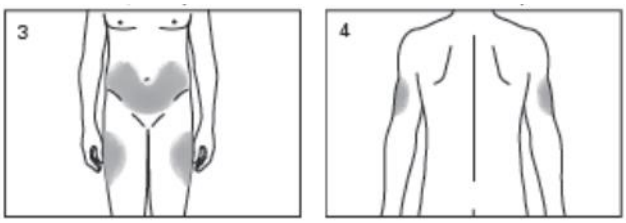


2. You may notice a small air bubble in the pre-filled syringe. If there are air bubbles present, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. With the syringe pointing upwards, expel all air from the syringe by pushing the plunger upwards.
3. The syringe 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).



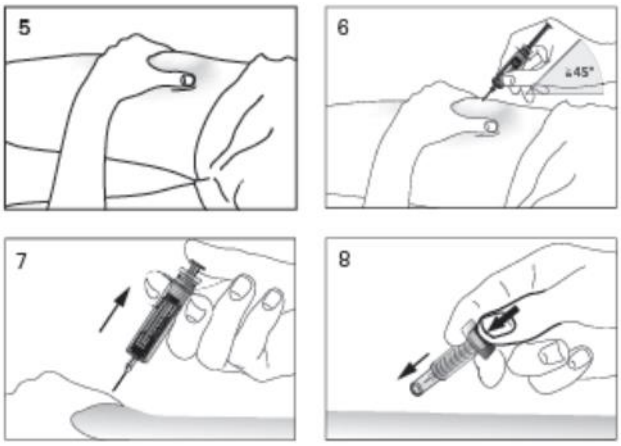
If someone else is injecting you, they can also use the back of your arms (see picture 4).

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 preservatives. 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.

PASIËNTINLIGTINGSBROSJURE

SKEDULERINGSTATUS: S4

FILGRASTIM TEVA 30, 30 MIU/0,5 mL oplossing vir inspuiting of infusie

FILGRASTIM TEVA 48, 48 MIU/0,8 mL oplossing vir inspuiting of infusie

Filgrastiem

Bevat suiker (Elke mL oplossing bevat 50 mg sorbitol)

Lees hierdie hele brosjure versigtig voordat jy begin om FILGRASTIM TEVA te gebruik:

- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, moet jy asseblief jou dokter of jou apteker vra.
- FILGRASTIM TEVA is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

WAT IN HIERDIE BLAD IS:

1. WAT FILGRASTIM TEVA IS EN WAARVOOR DIT GEBRUIK WORD

2. WAT U MOET WEET VOORDAT U FILGRASTIM TEVA DRINK

3. HOE OM FILGRASTIM TEVA TE GEBRUIK

4. MOONTLIKE NEWE-EFFEKTE

5. HOE OM FILGRASTIM TEVA TE BÊRE

6. INHOUD VAN DIE PAK EN ANDER INLIGTING

1. WAT FILGRASTIM TEVA IS EN WAARVOOR DIT GEBRUIK WORD:

FILGRASTIM TEVA bevat filgrastiem, 'n witbloedselgroeifaktor granulosietkoloniestimulerende faktor [G-CSF]). FILGRASTIM TEVA werk deur die beenmurg (die weefsel waar nuwe bloedselle gemaak

word) te stimuleer om meer witbloedselle te produseer. Witbloedselle is belangrik aangesien hulle jou liggaam help om infeksie te beveg.

FILGRASTIM TEVA word gebruik om die aantal witbloedselle na behandeling met chemoterapie te verhoog om infeksies te help voorkom.

2. WAT U MOET WEET VOORDAT U FILGRASTIM TEVA DRINK:

Moenie FILGRASTIM TEVA gebruik nie:

- indien jy hipersensitief (allergies) is vir filgrastiem of enige van die ander bestanddele van FILGRASTIM TEVA (gelys in **afdeling 6**)
- indien jy ernstige lae witbloedselvlakke het wat kort na jou geboorte gediagnoseer is (Kostmann se sindroom) met abnormale selstruktuur of - funksie
- indien jy nier- of lewerprobleme het
- indien jy swanger is of jou baba borsvoed.

Waarskuwings en Voorsorgmaatreëls:

Vertel jou dokter of gesondheidsorgdeskundige voordat jy ‘n inspuiting gegee word, indien:

Spesiale sorg moet geneem word met FILGRASTIM TEVA as:

- jy ‘n geskiedenis van sekelselsiekte het, omdat FILGRASTIM TEVA ‘n sekelselkrisis kan veroorsaak (‘n pynlike episode wat voorkom in persone wat sekelselanemie het. Rooibloedselle met die sekelsel-fatsoen blokkeer bloedvate. Bloed en suurstof kan nie die weefsels bereik nie, wat dan pyn veroorsaak)
- indien jy osteoporose (beensiekte) het. Jou dokter sal jou beenmineraaldigtheid moniteer indien jy vir langer as 6 maande FILGRASTIM TEVA ontvang
- as jy simptome van hoes, koors, kortasem of probleme met asemhaling het omdat dit tekens kan wees van 'n ernstige longprobleem genaamd Akute Respiratoriese Distress Sindroom (ARDS). Stop behandeling met FILGRASTIM TEVA onmiddellik en raadpleeg jou dokter as jy enige van hierdie simptome het (sien **Moontlike newe-effekte**).

'n Voorkankertoestand genaamd myelodisplastiese sindroom (MDS) of 'n tipe bloedkanker genaamd akute myeloïede leukemie (AML) is aangemeld met pegfilgrastiem, 'n medisyne soos FILGRASTIM

TEVA, wanneer dit in kombinasie met chemoterapie en/of radioterapie by bors- en longkankerpasiënte gebruik word. Alhoewel hierdie toestande nog nie met FILGRASTIM TEVA aangemeld is nie, sal jou dokter jou monitor vir tekens en simptome van MDS/AML, wat moegheid, koors en maklike kneusing of bloeding kan insluit.

Ander medisyne en FILGRASTIM TEVA:

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. Dit sluit alle komplementêre of tradisionele medisyne in.

Swangerskap en borsvoeding:

Indien jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige raadpleeg vir advies voordat jy FILGRASTIM TEVA gebruik.
FILGRASTIM TEVA is nie in swanger vrouens getoets nie.
FILGRASTIM TEVA behoort nie vir jou gegee te word nie indien jy swanger is of borsvoed.
Dit is onbekend of FILGRASTIM TEVA in borsmelk uitgeskei word. Jy behoort nie FILGRASTIM TEVA te gebruik indien jy borsvoed nie.

Bestuur en die gebruik van masjiene:

Dit is nie altyd moontlik om te voorspel tot watter mate FILGRASTIM TEVA met jou daaglikse aktiwiteite kan inmeng nie. U moet verseker dat u nie bestuur of masjinerie bestuur voordat u bewus is van die mate waarin FILGRASTIM TEVA u beïnvloed nie.
As jy moegheid (uiterste moegheid) ervaar, moenie bestuur of enige gereedskap of masjiene gebruik nie.

FILGRASTIM TEVA bevat sorbitol:

FILGRASTIM TEVA bevat 50 mg sorbitol in elke mL ('n tipe suiker).
Sorbitol is 'n bron van fruktose. As u (of u kind) Oorerflike Fruktose-Intoleransie (HFI), 'n seldsame genetiese afwyking, het, moet u (of u kind) nie hierdie medisyne ontvang nie. Pasiënte met HFI kan nie fruktose afbreek nie, wat ernstige newe-effekte kan veroorsaak. Jy moet jou dokter vertel voordat jy FILGRASTIM TEVA ontvang as jy (of jou kind) HFI het of as jou kind nie meer soet kos of drankies

kan neem nie omdat hulle siek voel, braak of onaangename effekte soos opgeblasenheid, maagkrampe of diarree kry.

3. HOE OM FILGRASTIM TEVA TE GEBRUIK:

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Jy moet altyd FILGRASTIM TEVA presies volgens jou dokter se instruksies gebruik.
Jy behoort met jou dokter of apteker te gesels as jy onseker is.

Die gewone dosis:

FILGRASTIM TEVA word gewoonlik as ‘n daaglikse inspuiting in die weefsel net onder die vel gegee (bekend as ‘n subkutane inspuiting). Dit kan ook as ‘n daaglikse stadige inspuiting in ‘n vene gegee word (bekend as ‘n intraveneuse infusie). Die dosering sal wissel afhangende van jou siekte en gewig.
Jou dokter sal vir jou vertel hoeveel FILGRASTIM TEVA aan jou toegedien sal word.
Jy sal FILGRASTIM TEVA ontvang totdat jou witbloedseltelling normaal is.
Gereelde bloedtoetse sal gedoen word om die getal witbloedselle in jou liggaam te moniteer.

Indien jy onder die indruk verkeer dat die effek van FILGRASTIM TEVA te sterk of te swak is, moet jy jou dokter of apteker daarvan vertel. Dit is normaal om ‘n aantal kursusse FILGRASTIM TEVA behandeling te ontvang.

Die gebruiklike dosis is 0,5 miljoen internasionale eenhede (MIE) per kilogram liggaamsgewig elke dag.

Jou behandeling sal gewoonlik vir ongeveer 14 dae duur. In sommige siektesoorte, mag langer behandeling wat tot een maand mag duur, nodig wees.

Metode van toediening:

Indien jy hierdie medisyne deur middel van subkutane inspuiting ontvang, mag jou dokter voorstel dat jy leer hoe om jouself die inspuiting te gee. Jou dokter of verpleegster sal vir jou instruksies gee oor

hoe om dit te doen. Moenie self-toediening probeer sonder hierdie opleiding nie. Sommige van die inligting wat jy nodig het, word aan die einde van hierdie brosjure gegee, maar korrekte behandeling van jou siekte verg noue en konstante koöperasie met jou dokter.
Jy moet alle afsprake vir jou FILGRASTIM TEVA inspuitings en bloedtoetse nakom.
Elke voorafgevulde spuit is alleenlik vir eenmalige gebruik bedoel.

Indien jy meer FILGRASTIM TEVA gebruik, as nodig:

In ‘n geval van oordosering moet jy jou dokter of apteker raadpleeg. Indien beide nie beskikbaar is nie, moet jy die naaste hospitaal of gifbeheersentrum kontak.

Indien jy vergeet om FILGRASTIM TEVA te gebruik:

Moenie ‘n dubbele dosis gebruik, om op te maak vir ‘n vergete inspuiting nie.

Effekte wanneer behandeling met FILGRASTIM TEVA gestaak word:

Voordat jy die gebruik van FILGRASTIM TEVA staak, moet jy met jou dokter gesels.

4. MOONTLIK NEWE-EFFEKTE:

FILGRASTIM TEVA kan newe-effekte veroorsaak.
Nie alle newe-effekte wat vir FILGRASTIM TEVA aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou vererger of as jy enige nadelige effekte ondervind terwyl jy hierdie medisyne neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

Indien enige van die volgende sou gebeur, moet jy die inname van FILGRASTIM TEVA staak en jou dokter dadelik vertel of na die noodafdeling van jou naaste hospitaal gaan:

- swakheid, val in bloeddruk, probleme met asemhaling, swelling van die gesig (anafilakse)
- veluitslag, jeukerige veluitslag (urtikarie)
- swelling van die gesig, lippe, tong of keel (angio-edeem)
- kortasem (dispnee).

Dit is almal baie ernstige newe-effekte. Indien jy dit ontwikkel, het jy moontlik ‘n ernstige allergiesie reaksie teen FILGRASTIM TEVA gehad. Jy het dalk dringende mediese aandag of hospitalisasie nodig.

Vertel jou dokter dadelik of gaan na die noodafdeling by jou naaste hospitaal indien jy van enige van die volgende bewus word:

- hoes, koors en probleme met asemhaling omdat dit ‘n teken van Akute Respiratoriese Noodsindroom (ARDS) mag wees
- ernstige pyn in die bene, bors, buik of gewrigte (sekelselkrisis).

Dit is almal ernstige newe-effekte. Jy het dalk dringende mediese aandag nodig.

Vertel jou dokter indien jy van enige van die volgende nadelige effekte bewus word:

Gereelde newe-effekte:

- naarheid (voel siek)
- braking
- hardlywigheid
- diarree
- gebrek aan aptyt (anoreksie)
- hoofpyn
- seer keel
- uitermatige moegheid (uitputting), algemene swakheid
- haarverlies
- borspyn
- muskuloskeletale pyn.

Vertel jou dokter indien jy enige van die volgende bewus word:

Minder gereelde newe-effekte:

Enige van die volgende of kombinasie van die volgende nadelige effekte:

- swelling of geswollenheid, wat geassosieer mag wees met verminderde urinering, probleme met asemhaling, abdominale swelling en gevoel van volheid, en ‘n algemene gevoel van

moegheid. Dit kan moontlik simptome van ‘n ongewone toestand genoem Kapillêre Lek-Sindroom wees, wat lekkasie van bloed uit die klein bloedvate in jou liggaam veroorsaak en dringend mediese aandag nodig het

- vaskulêre versteuring (‘n versteuring wat die bloedvate affekteer)
- pseudo-jig (‘n soort artritis wat pyn, styfheid, teerheid, rooiheid, warmte en swelling in sommige gewigte veroorsaak)
- abnormale X-straalbeelde van die long (Pulmonale infiltrate)
- inflammasie van die bloedvate in die vel (kutane vaskulitis)
- sweets se sindroom (pruimkleurige, verhewe, pynlike sere op die ledemate en soms op die gesig en nek met koors)
- verergering van rumatoïede artritis
- pynlike of moeilike urinering of probleme met urinering.

Indien jy van enige newe-effekte bewus word, wat nie in hierdie brosjure genoem word nie, moet jy asseblief jou dokter of apteker daarvan vertel.

Rapportering van newe-effekte:

As jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **6.04 Adverse Drug Reaction Reporting Form**, aanlyn gevind onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.

Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van FILGASTRIM TEVA te verskaf.

5. HOE OM FILGRASTIM TEVA TE BÊRE:

Bewaar tussen 2 °C tot 8 °C in ‘n yskas.

Bewaar alle medisyne buite bereik van kinders.

Moenie FILGRASTIM TEVA na die vervaldatum wat op die buitenste karton en op die voorafgevulde spuit genoem word, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Moenie FILGRASTIM TEVA gebruik nie, indien jy bewus word daarvan dat dit wolkerig is of as daar partikels daarin is. Elke voorafgevulde spuit is slegs vir eenmalige gebruik bedoel. Toevallige blootstelling aan vries temperature affekteer nie die stabiliteit van FILGRASTIM TEVA nadelig nie.

Medisyne behoort nie in afvalwater of huishoudelike afval weggegooi te word nie. Vra jou apteker hoe om van medisyne wat nie langer benodig word nie, ontslae te raak. Hierdie maatreëls sal help om die omgewing te beskerm.

6. INHOUD VAN DIE PAK EN ANDER INLIGTING:

Wat FILGRASTIM TEVA bevat:

Die aktiewe bestanddeel is filgrastiem. Elke mL oplossing vir inspuiting of infusie bevat 60 miljoen internasionale eenhede [MIU] (600 µg) filgrastiem.

FILGRASTIM TEVA 30: Elke voorafgevulde spuit bevat 30 MIU (300 µg) filgrastiem in 0,5 mL oplossing of infusie.
FILGRASTIM TEVA 48: Elke voorafgevulde spuit bevat 48 MIU (480 µg) filgrastiem in 0,8 mL oplossing of infusie.

Die ander bestanddele is asynsuur, polisorbaat 80 en water vir inspuitings. Elke mL oplossing bevat 50 mg sorbitol.

Hoe FILGRASTIM TEVA lyk en inhoud van die verpakking:

FILGRASTIM TEVA is 'n helder kleurlose oplossing, feitlik vry van deeltjies.
Verdunde oplossing: Helder, kleurlose oplossing vry van sigbare deeltjies.

FILGRASTIM TEVA 30 is beskikbaar in Tipe I helder, kleurlose voorafgevulde glasspuite met ‘n groen polipropileen plunjerstang en ‘n grys broombutiel rubberplunjerprop, voorsien met ‘n permanent aangehegte vlekvrye staalnaald met, of sonder, ‘n kleurlose veiligheidtoestel wat naaldsteekbesering en hergebruik moet verhoed.
Beskikbaar in kartondoosverpakkings wat 1, 5, of 10 voorafgevulde spuite bevat, met 0,5 mL oplossing; of Veelvoudige-verpakkings wat 10 (2 verpakkings van 5) voorafgevulde spuite bevat, met 0,5 mL oplossing.

FILGRASTIM TEVA 48 is beskikbaar in Tipe I helder, kleurlose voorafgevulde glasspuite met ‘n blou polipropileen plunjerstang en ‘n grys broombutiel rubberplunjerprop, voorsien met ‘n permanent aangehegte vlekvrye staalnaald met, of sonder, ‘n kleurlose veiligheidtoestel wat naaldsteekbesering en hergebruik moet verhoed.
Beskikbaar in kartondoosverpakkings wat 1, 5, of 10 voorafgevulde spuite bevat met 0,8 mL oplossing; of Veelvoudige-verpakkings wat 10 (2 verpakkings van 5) voorafgevulde spuite bevat, met 0,8 mL oplossing.

Die spuite met die veiligheidtoestelle word binne in kartonne, of as hitte-gevormde PVC stolpverpakkingsblasies met ‘n papier-agtergrond of in plastiekbakke verdeel in vakkies, met een spuit per blasie of vakkie, verpak.
Spuite sonder veiligheidtoestelle word in kartondose met kartonbakke verpak.

Nie alle verpakkingsgroottes sal bemark word nie.

Houer van Registrasie sertifikaat:

Teva Pharmaceuticals (Pty) Ltd
Maxwell Office Park
Magwa Singelwes
Waterfall City
Midrand
Gauteng
Suid-Afrika
2090
Tel: (011) 055 0200

Hierdie pamflet is laas hersien in:

22 Junie 2023

Registrasienommers:

FILGRASTIM TEVA 30: 46/32.16/0317

FILGRASTIM TEVA 48: 46/32.16/0318

INLIGTING OM JOUSELF IN TE SPUIT

Hierdie afdeling bevat inligting oor hoe jy vir jouself ‘n inspuiting van FILGRASTIM TEVA moet gee. Dit is belangrik dat jy nie probeer om jouself ‘n inspuiting te gee nie, tensy jy spesiale opleiding van jou dokter of verpleegster ontvang het. Indien jy nie seker is oor hoe om vir jouself ‘n inspuiting te gee nie, of as jy vrae het, moet jy asseblief jou dokter of verpleegster vir hulp vra.

FILGRASTIM TEVA word in voorafgevulde spuite met, of sonder veiligheidtoestel, verskaf. Die figure hierna verwys of na spuite met ‘n veiligheidstoestel (figure 2a, 2b, 7 en 8) of daarsonder (figure 1a en 1b). Die ander figures (3, 4, 5, 6) is op albei spuite van toepassing. Jou dokter of apteker kan vir jou vertel watter voorafgevulde spuit jy ontvang het. Dit is belangrik dat jy van die spuit sonder veiligheidstoestel ontslae raak in ‘n houer wat nie deursteek kan word nie.

Hoe moet ek myself met FILGRASTIM TEVA inspuit?

Jy sal die inspuiting in die weefsel net onder die vel moet gee. Dit is bekend as ‘n subkutane inspuiting. Jy moet jou inspuitings op ongeveer dieselfde tyd elke dag toedien.

Gereedskap wat jy nodig het:

Om vir jouself ‘n subkutane inspuiting te gee, sal jy die volgende nodig hê:

- ‘n voorafgevulde FILGRASTIM TEVA spuit
- alkoholdeppers of soortgelyk
- ‘n houer wat nie deursteek kan word nie (‘n plastiekhouer wat deur die hospitaal of apteek verskaf word) sodat jy van gebruikte spuite sonder veiligheidtoestelle veilig kan ontslae raak.

Wat behoort ek te doen voordat ek myself ‘n subkutane inspuiting met FILGRASTIM TEVA gee?

1. Probeer om self-inspuitings op ongeveer dieselfde tyd elke dag toe te dien.
2. Neem jou voorafgevulde FILGRASTIM TEVA spuit uit die yskas.

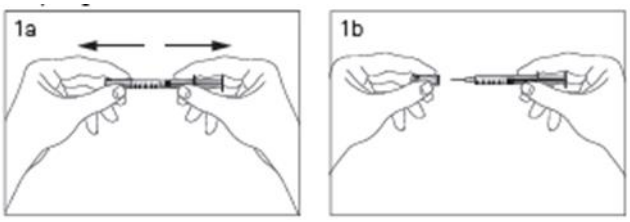
3. Kontroleer die vervaldatum op die etiket van die voorafgevulde spuit (EXP). Moenie dit gebruik nie indien die datum later is as die laaste dag van die maand wat aangetoon word.
4. Kontroleer die voorkoms van FILGRASTIM TEVA. Dit moet ‘n helder en kleurlose vloeistof wees. Indien dit partikels bevat, moet jy dit nie gebruik nie.
5. Vir ‘n meer gemaklike inspuiting, moet jy die voorafgevulde spuit vir 30 minute laat staan om kamertemperatuur te bereik of hou die voorafgevulde spuit sagkens in jou hand vir ‘n paar minute. Moenie FILGRASTIM TEVA op enige ander manier verwarm nie (byvoorbeeld, moenie dit in ‘n mikrogolfoond of in warm water verwarm nie).
6. Moenie die dop van die spuit verwyder nie totdat jy gereed is om in te spuit.
7. Was jou hande deeglik.
8. Vind ‘n gemaklike, goed beligte plek en sit alles wat jy nodig het waar jy dit kan bykom (die FILGRASTIM TEVA voorafgevulde spuit, alkoholdeppers en die ondeurdringbare houer).

Hoe moet ek my FILGRASTIM TEVA inspuiting voorberei?

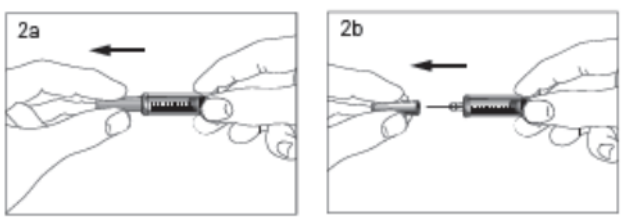
Voordat jy FILGRASTIM TEVA inspuit, moet jy die volgende doen:

1. Hou die spuit vas en verwyder die dop van die naald sagkens sonder om dit te draai. Trek dit reguit af, soos in figure 1 en 2 aangedui (see figure 1a en 1b vir spuite sonder veiligheidstoestel en figure 2a en 2b vir spuite met veiligheidstoestel). Moenie aan die naald raak, of die plunjer stoot nie.

   Sonder veiligheidstoestel:



   Met veiligheidstoestel:

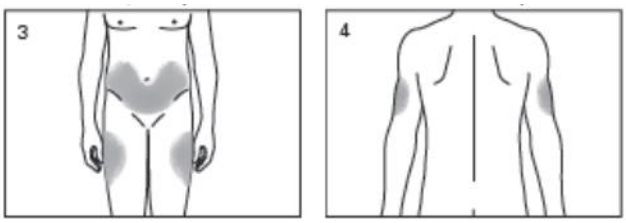


2. Jy mag bewus word van ‘n klein lugborrel in die voorafgevulde spuit. Indien lugborrels teenwoordig is, tik sagkens met jou vingers op die spuit totdat die lugborrels tot die boonste deel van die spuit styg. Terwyl die spuit boontoe wys, moet jy alle lug uit die spuit uitstoot deur die plunjer opwaarts te stoot.
3. Die spuit het ‘n skaal op die romp van die spuit. Druk die plunjer tot die nommer (mL) op die spuit wat ooreenstem met die dosis FILGRASTIM TEVA wat jou dokter voorgeskryf het.
4. Maak weer seker dat die korrekte dosis FILGRASTIM TEVA in die spuit is.
5. Jy kan nou die voorafgevulde spuit gebruik.

Waar behoort ek my inspuiting toe te dien?

Die mees geskikte plekke om jouself in te spuit is:

- die bokant van jou dye; en
- die buik, behalwe die gebied rondom die naeltjie (sien prentjie 3).



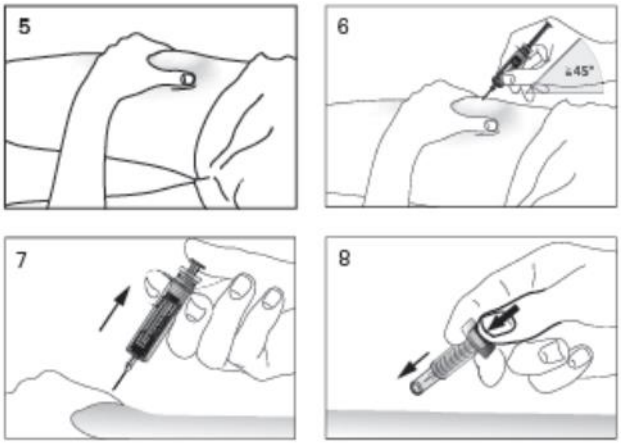
Indien iemand anders jou inspuit, kan hulle ook die agterkant van jou arms gebruik (sien prentjie 4).
Dit is beter om die inspuitingsplek elke dag te verander om die risiko van seerheid op enigeen van die inspuitplekke te vermy.

Hoe moet ek my inspuiting gee?

1. Ontsmet die inspuitingsplek deur gebruik te maak van ‘n alkoholdepper en knyp die vel tussen jou duim en wysvinger vas te knyp, sonder om dit te druk (sien prentjie 5).
2. Voer die naald ten volle in die vel in soos jou verpleegster of dokter vir jou gewys het (sien prentjie 6).
3. Trek effens op die plunjer om seker te maak dat geen bloedvat raak gesteek is nie. Indien jy bloed in die spuit sien, moet jy dit verwyder en dit op ‘n ander plek weer invoer.
4. Spuit die vloeistof stadig en eweredig in, terwyl jy jou vel steeds vasgeknyp hou.
5. Spuit net die dosis in wat jou dokter aanbeveel het.

6. *Spuit sonder veiligheidstoestel*: Na inspuiting van die vloeistof, moet die naald verwyder word en jy moet jou vel loslaat.

   Spuit met veiligheidstoestel: Verwyder die spuit van die inspuitingsplek terwyl jy jou vinger op die plunjer hou (sien prentjie 7). Hou die naald weg van jou en ander persone, en aktiveer die veiligheidtoestel deur die plunjer ferm te druk (sien prentjie 8). Jy sal ‘n “klikgeluid” hoor wat aktivering van die veiligheidstoestel bevestig. Die naald sal deur die beskermende huls bedek wees sodat jy jouself nie kan steek nie.
7. Jy moet elke spuit slegs vir een inspuiting gebruik. Moenie enige van die oorblywende FILGRASTIM TEVA in die spuit gebruik nie.



Met veiligheidstoestel

Onthou: Indien jy enige probleme het, moet asseblief nie huiwer om jou dokter of verpleegster vir hulp en advies te vra nie.

Wegdoening van gebruikte spuite:

Spuite sonder veiligheidstoestel:

- Moenie die dop op gebruikte naalde terugsit nie.
- Sit die spuite in die ondeurdringbare houer en bewaar hierdie houer buite bereik en sig van kinders.
- Raak ontslae van die ondeurdringbare houer wanneer dit vol is volgens jou dokter, verpleegster of apteker se instruksies.
- Moet nooit die spuite wat jy gebruik het in jou normale huishoudelike vullisblik sit nie.

Spuite met ‘n veiligheidstoestel:

- Die veiligheidstoestel verhoed naaldsteekbeserings na gebruik, dus is geen spesiale voorsorgmaatreëls vir wegdoening nodig nie. Raak van spuite met ‘n veiligheidstoestel ontslae volgens jou dokter, verpleegster of apteker se instruksies.

DIE VOLGENDE INLIGTING IS ALLEENLIK VIR MEDIESE OF GESONDHEIDSORGDESKUNDIGES BEDOEL

FILGRASTIM TEVA bevat geen preserveermiddel nie. Weens die moontlike risiko van mikrobiese besmetting, is FILGRASTIM TEVA spuite alleenlik bedoel om een keer gebruik te word.

Toevallige blootstelling aan vries temperature affekteer nie die stabiliteit van FILGRASTIM TEVA nadelig nie.

FILGRASTIM TEVA behoort nie met natriumchloriedoplossing verdun te word nie. Hierdie medisinale produk moet nie met ander medisinale produkte gemeng word nie behalwe dié wat hierna genoem word. Verdunde FILGRASTIM TEVA mag op glas en plastiek materiale geadsorbeer word, tensy dit verdun word soos hierna beskryf.

Indien nodig, kan FILGRASTIM TEVA verdun word in glukose 50 mg/mL (5 %) oplossing vir infusie. Verdunning tot ‘n finale konsentrasie van minder as 0,2 MIE (2 µg) per mL word nie te eniger tyd aanbeveel nie. Die oplossing moet visueel ondersoek word voor gebruik. Slegs helder oplossings sonder partikels behoort gebruik te word.
Vir pasiënte wat behandel word met FILGRASTIM TEVA wat tot 1,5 MIE (15 µg) per mL verdun is, behoort menslike serumalbumien (HSA) bygevoeg te word tot ‘n finale konsentrasie van 2 mg/mL. Voorbeeld: In ‘n finale inspuitingsvolume van 20 mL, behoort totale dosisse van filgrastiem van minder as 30 MIE (300 µg), saam met bygevoegde 0,2 mL van ‘n 200 mg/mL (20 %) menslike albumienoplossing, toegedien te word. Wanneer dit in glukose 50 mg/mL (5 %) oplossing vir infusie

verdun is, is FILGRASTIM TEVA verenigbaar met glas en ‘n verskeidenheid soorte plastiek, insluitend PVC, poliolefien (‘n kopolimeer van polipropileen en poliëtileen) en polipropileen.

Na verdunning: Chemiese en fisiese in-gebruik stabiliteit van die verdunde oplossing vir infusie is vir 24 uur tussen 2 °C tot 8 °C gedemonstreer. Uit ‘n mikrobiologiese oogpunt beskou, behoort die produk dadelik gebruik te word. Indien dit nie dadelik gebruik word nie, is die in-gebruik bergingstye en toestande voor gebruik die verantwoordelikheid van die gebruiker en dit behoort normaalweg nie langer as 24 uur tussen 2 °C tot 8 °C te wees nie.