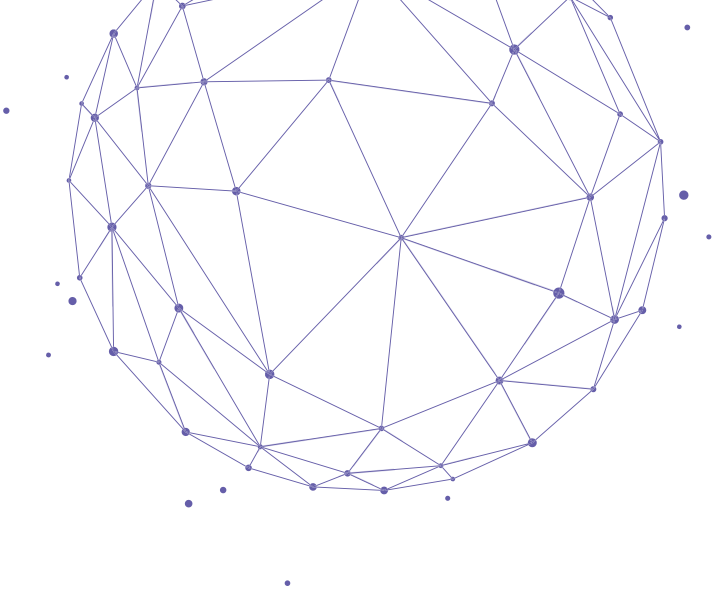
Patient Information

Cipla TEVA

Filgrastim Teva



Patient Guide:

Understanding how FILGRASTIM TEVA injection may help you during chemotherapy

Read this whole leaflet carefully before you start using FILGRASTIM TEVA:

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

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 (neutrophils). 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[1]

Neutropenia

Neutropenia is an abnormally low level of neutrophils. Neutrophils are a common type of white blood cell important for fighting off infections — particularly those caused by bacteria.

Cancer chemotherapy is probably the most common cause of neutropenia. People with chemotherapy-related neutropenia are prone to infections while they wait for their cell counts to recover.

Neutrophils are manufactured in bone marrow — the spongy tissue inside some of your larger bones. Anything that disrupts neutrophil production can result in neutropenia[2].

Signs and symptoms of neutropenia[3]

Neutropenia itself may not cause any symptoms. Patients usually find out they have neutropenia from a blood test or when they get an infection. Some people will feel more tired when they have neutropenia. Your doctor will schedule regular blood tests to look for neutropenia and other blood-related side effects of chemotherapy.

For patients with neutropenia, even a minor infection can quickly become serious. Talk with your health care team right away if you have any of these signs of infection:

- A fever, which is a temperature of 38 °C or higher
- Chills or sweating
- Sore throat, sores in the mouth, or a toothache
- Abdominal pain
- Pain near the anus
- Pain or burning when urinating, or urinating often
- Diarrhoea or sores around the anus
- A cough or shortness of breath
- Any redness, swelling, or pain (especially around a cut, wound, or catheter)
- Unusual vaginal discharge or itching

What you need to know before you use Filgrastim Teva?[1]

Do not use FILGRASTIM TEVA:

- If you are hypersensitive (allergic) to filgrastim or any of the other ingredients of FILGRASTIM TEVA.
- 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.

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

- You have a history of 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. Because of this, 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.

Take special care with FILGRASTIM TEVA 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.

Possible side effects of Filgrastim Teva[1]

FILGRASTIM TEVA can have side effects.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking 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 (urticaria)
- 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.

Side effects that may occur frequently[1]

- Nausea (feeling sick)
- Vomiting
- Constipation
- Diarrhoea
- Lack of appetite
- Headache
- Sore throat
- Extreme tiredness (fatigue), general weakness
- Hair loss
- Chest pain
- Musculoskeletal pain

Information about other less frequently occurring side effects are included in the package insert enclosed in the FILGRASTIM TEVA carton.

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

Information for injecting yourself[1]

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.

How do I inject Filgrastim Teva myself?[1]

You will need to give yourself an 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.

FILGRASTIM TEVA is supplied in packs of 5 pre-filled syringes each fitted with a safety device.

FILGRASTIM TEVA should be stored between 2°C – 8°C in a refrigerator.

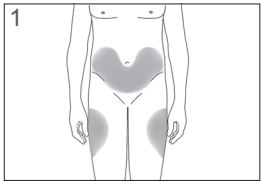
For a more comfortable injection, take your FILGRASTIM TEVA pre-filled syringe out of the refrigerator and let the pre-filled syringe stand for 30 minutes to reach room temperature or hold the pre-filled syringe gently in your hand for a few minutes. Do not warm FILGRASTIM TEVA in any other way (for example, do not warm it in a microwave or in hot water).

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.

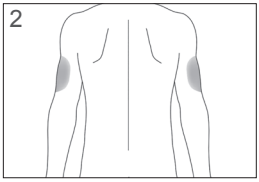
Do not remove the cover from the syringe until you are ready to inject.

Wash your hands thoroughly.

- **The most suitable places to inject yourself are:**
  - the top of your thighs; and
  - the abdomen, except for the area around the navel.

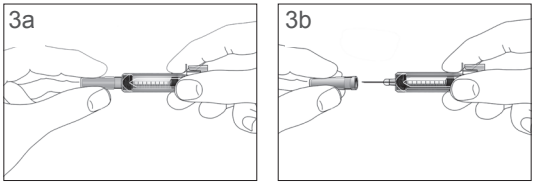


- **If someone else is injecting you, they can also use the back of your arms.**



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

- **Hold the syringe and gently take the cover from the needle without twisting. Do not touch the needle or push the plunger.**

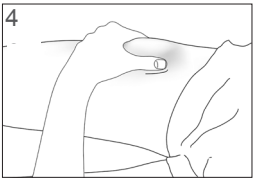


You may notice a small air bubble in the pre-filled syringe. If there are air bubbles present, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. With the syringe pointing upwards, expel all air from the syringe by pushing the plunger upwards.

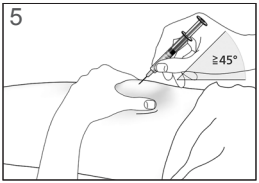
The syringe has a scale on the syringe barrel. Push the plunger up to the number (ml) on the syringe that matches the dose of FILGRASTIM TEVA that your doctor prescribed. Check again to make sure the correct dose of FILGRASTIM TEVA is in the syringe.

You can now use the pre-filled syringe.

- **Disinfect the injection site by using an alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it.**

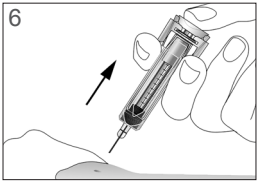


- **Put the needle fully into the skin as shown by your nurse or doctor, at a 45° angle.**



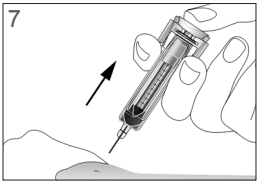
Pull slightly on the plunger to check that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and re-insert it in another place.

Inject the liquid slowly and evenly, always keeping your skin pinched.

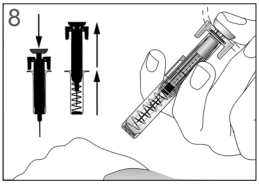


Inject only the dose your doctor has told you.

- **Remove the syringe from the injection site while keeping your finger on the plunger.**



- **Direct the needle away from you and others and activate the safety device by firmly pushing the plunger.**



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.

Only use each syringe for one injection. Do not use any FILGRASTIM TEVA that is left in the syringe.

Disposing of used syringes[1]:

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.

Please contact your healthcare treatment team with any questions that you may have.

References:

1. Package Insert (Patient information Leaflet) 27 November 2017.
2. Neutropenia. Available at: https://www.mayoclinic.org/symptoms/neutropenia/basics/definition/sym-20050854.
3. Neutropenia. Available at: https://www.cancer.net/navigating-cancer-care/side-effects/neutropenia."

S4 FILGRASTIM TEVA 30 (Solution for injection or infusion). Reg. No.: 46/32.16/0317.
S4 FILGRASTIM TEVA 48 (Solution for injection or infusion). Reg. No.: 46/32.16/0318.

Each pre-filled syringe contains 30 MIU (300 µg) or 48 MIU (480 µg) of filgrastim in 0,5 ml or 0,8 ml of solution for injection or infusion respectively. For full prescribing information please refer to the package insert approved by the medicines regulatory authority.
TEVA PHARMACEUTICALS (PTY) LTD. Co. Reg. No. 1986/002796/07. Maxwell Office Park, Magwa Crescent West, Waterfall City, Midrand, 2090. Tel: +27 11 055 0200, Fax: +27 86 680 8988.
Marketed by CIPLA MEDPRO (PTY) LTD. Co. Reg. No. 1995/004182/07.
Building 9, Parc du Cap, Mispel Street, Bellville, 7530, RSA.
Website: www.cipla.co.za Customer Care: 080 222 6662.
[13602] ATC307/06/18