

TEVAGRASTIM®

filgrastim (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TEVAGRASTIM.

Please note that this leaflet does not contain everything there is to know about TEVAGRASTIM. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has prescribed TEVAGRASTIM after considering its likely benefit to you, as well as the potential risks.

If you have any concerns about taking this medicine, talk to your doctor, nurse or pharmacist.

Keep this leaflet with your medicine.

You may need to read this information again.

What TEVAGRASTIM is used for

Your doctor may have prescribed TEVAGRASTIM because:

1. **You are receiving chemotherapy for cancer**

Unfortunately, some chemotherapy will reduce the number of neutrophils in your body. Although TEVAGRASTIM is not a treatment for cancer, it does help the body to make new neutrophils and this will reduce your chance of developing infections that might require antibiotics and/or hospital stays. It may even increase your chance of receiving your chemotherapy on time and at the right dose.

2. **You are receiving a bone marrow or stem cell transplant**

Blood cells are produced in the bone marrow and arise from special 'parent' cells, called stem cells. Some chemotherapy has toxic effects on bone marrow, so your doctor may choose to collect stem cells from your bone marrow or blood - or from a donor's bone marrow or blood - before you receive your chemotherapy. These collected stem cells are then stored and may be given back to you later, to replace those lost during chemotherapy. This procedure is called a bone marrow or stem cell transplant.

There are normally only a small number of stem cells in your blood; TEVAGRASTIM is typically used to increase this number before stem cell collection. You may also receive TEVAGRASTIM after a bone marrow or stem cell transplant, to help speed up your recovery.

3. **You are donating stem cells for another person**

If you are aged between 16 and 60 years and have volunteered to donate your stem cells for another person, TEVAGRASTIM may be used to increase the number of stem cells in your blood before they are collected. Your stem cells can then be given to a patient after he/she has received their chemotherapy.

4. **You are suffering from severe chronic neutropenia**

Severe chronic neutropenia is a disease in which the body does not make enough neutrophils, increasing your risk of fever and/or infection. TEVAGRASTIM helps the body to make and maintain the right number of infection-fighting neutrophils, decreasing the risk of infection and the need for antibiotics and/or hospital stays.

5. **You are receiving medicines for HIV infection**

Some medicines used to treat HIV (Human Immuno-deficiency Virus) infection, or its complications, can reduce the number of infection-fighting neutrophils in your blood. Your doctor may prescribe TEVAGRASTIM if the number of neutrophils falls too low. By boosting your neutrophil count, TEVAGRASTIM will improve your body's ability to fight infection and may increase your chance of receiving the full dose of some of your HIV medicines. TEVAGRASTIM is not a treatment for HIV infection.

How it works

TEVAGRASTIM - also known as Filgrastim (rbe) - is a copy of a substance normally present in your body, called Granulocyte Colony Stimulating Factor or G-CSF. Using gene technology, TEVAGRASTIM is produced in a specific type of bacteria, called *E. coli*.

G-CSF is produced in the bone marrow and assists in the production of neutrophils, which are a type of white blood cell. Neutrophils help the body fight infections by surrounding and destroying the bacteria that cause them. G-CSF also helps neutrophils to do this work better.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use TEVAGRASTIM

When you must not use *Tevagrastim*

Do not have TEVAGRASTIM if you have had an allergy to:

- **TEVAGRASTIM or any of the ingredients listed at the back of this leaflet**
- **medicine or any other products that are produced by DNA technology using the bacteria *E. coli*.**

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives.

Do not use TEVAGRASTIM at the same time as your chemotherapy or radiotherapy.

Do not use TEVAGRASTIM in the 24 hours before or the 24 hours after you receive your chemotherapy, radiotherapy, bone marrow transplant or stem cell transplant.

This is because these types of treatments may stop TEVAGRASTIM from increasing the number of infection-fighting neutrophils.

Do not use TEVAGRASTIM after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

Do not use TEVAGRASTIM if it has been left out of the refrigerator for more than three days.

If you are not sure whether you should use *Tevagrastim*, talk to your doctor or pharmacist.

Before you start to use TEVAGRASTIM

Tell your doctor if you have allergies to:

- **any other medicines**

- **any other substances, such as foods, preservatives or dyes.**

Tell your doctor if you are pregnant or intend to become pregnant or are breastfeeding.

Tell your doctor if you:

- have a medical condition affecting the bone marrow or blood
- have a family history of a genetic disorder
- suffer from sickle cell disease
- have problems with your kidneys, liver, heart or other organs
- have had previous treatment for cancer
- have any infections, cancers or tumours.

If you have not told your doctor about any of these things, tell him/her before you use any TEVAGRASTIM. Your doctor will decide whether it is safe for you to use TEVAGRASTIM.

There is limited experience with the use of TEVAGRASTIM in children.

Your doctor will discuss the risks and benefits of using it in children.

Taking other medicines

Tell your doctor if you are taking any other medicines, particularly those that may affect the blood. Also tell him/her about those you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use TEVAGRASTIM

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions ask your doctor, nurse or pharmacist for help.

TEVAGRASTIM is given by injection, usually into the tissues just below the skin. This is called a subcutaneous injection and it is a simple procedure.

Your doctor, nurse or pharmacist may suggest that you or your carer be taught how to give a subcutaneous injection. This will allow you to have your TEVAGRASTIM injection at home.

TEVAGRASTIM is sometimes given by injection into a vein. This is called an intravenous injection and is generally given by a doctor or nurse.

How much to inject

Your doctor will tell you the strength of TEVAGRASTIM you need and how much you require. How much you need will depend on the reason for your treatment, your body weight and the number of neutrophils in your blood.

For TEVAGRASTIM to work properly, you have to use it exactly as your doctor has instructed.

Where to inject

The best injection sites are:

- your abdomen, except for the area around the navel (belly button) or
- the front or side of your thighs.

Change the injection site each time you inject to avoid soreness at any one site.

When to inject

For best results, you should inject TEVAGRASTIM at about the same time each day. Your doctor will tell you when to begin your treatment and when to stop.

How long to use it

Patients receiving chemotherapy or who have received a bone marrow or stem cell transplant are only required to use TEVAGRASTIM for short periods of time until the number of infection-fighting neutrophils are restored (usually 1 to 3 weeks). Stem cell donors should receive TEVAGRASTIM treatment for 4 to 5 days. Patients with severe chronic neutropenia are required to use TEVAGRASTIM regularly and for a long period of time, to keep the number of infection-fighting neutrophils at a normal level.

Patients with HIV infection need to use TEVAGRASTIM daily until their neutrophil numbers are normal. Usually, the dose is then reduced to three injections per week to maintain the neutrophil numbers. Your doctor will tell you how many injections you need each week and on which days they should be given.

Things to do before you inject

Make sure that you have all the materials you need for your injection:

- a new TEVAGRASTIM syringe
- an alcohol swab
- a puncture-resistant sharps container.

Follow these instructions exactly to help avoid contamination and possible infection. If you are unsure, check with your doctor, nurse or pharmacist.

1. Find a clean, flat working surface, such as a table, where you can inject undisturbed.
2. Remove the syringe from the refrigerator. For a more comfortable injection, leave at room temperature for approximately 30 minutes. Do not warm TEVAGRASTIM in any other way (e.g. do not warm in the microwave or in hot water).
3. Check that the syringe has not been used before.
4. Do not shake the syringe. If the TEVAGRASTIM solution appears frothy or bubbly, allow the syringe or vial to sit undisturbed for a few minutes to reduce the froth or bubbles before measuring your dose.
5. Do not remove the needle cover until you are ready to inject.
6. Check the expiry date on the label. Do not use if the date has passed the last day of the month shown.
7. Check the appearance of the solution. The solution should be clear and colourless. If it is cloudy, coloured or if there are clumps or flakes, you must not use it.
8. Wash and dry your hands thoroughly.

How to prepare your injection

1. Hold the syringe vertically with the needle pointing up - this helps reduce the amount of medicine that may leak out of the needle. Carefully remove the needle cover, taking care not to touch the exposed needle.
2. Check the dose (in mL) that your doctor has prescribed and locate the correct volume mark on the syringe barrel. Carefully push the plunger until the grey upper edge of the plunger reaches the correct volume mark. This will push the air and any excess liquid out of the syringe.
3. Double-check that you have the correct dose.

How to inject

1. Clean the site where the injection is to be made with an alcohol swab, moving the alcohol swab in an expanding circle and allow the site to dry.

2. Pinch a large area of skin between your thumb and forefinger, to create a firm injection site.
3. Pick up the syringe and hold it as you would a pencil.
4. Insert the needle directly into the skin (at an angle of between 45 degrees and 90 degrees or as advised by your doctor, nurse or pharmacist).
5. After the needle is in, pull back the plunger very slightly. If blood comes into the syringe, the needle has entered a blood vessel. Remove the needle. Select another site, clean the new site with an alcohol swab and reinsert the needle. Again, pull back the plunger very slightly to check for blood. If blood does not appear in the syringe, inject the TEVAGRASTIM by gently pushing the plunger all the way in.
6. Withdraw the needle and using the alcohol swab apply pressure for several minutes to the injection site.
7. Do not put the needle cover back on the used syringe. You cannot reuse the syringe.
8. Discard the used syringe into an approved, puncture-resistant, sharps container.

Do not change the dose or the way you inject TEVAGRASTIM without consulting your doctor. Always follow your doctor's instructions.

If you forget your injection

If you miss your scheduled dose, inject it as soon as you can - provided that it is still on the same day.

If you miss a WHOLE DAY before you remember to inject yourself, do not take a 'catch-up' dose or increase your next dose. Advise your doctor, nurse or pharmacist as soon as possible about the missed dose.

If you inject too much (overdose)

If you inject more than the dose recommended by your doctor you should contact your doctor, nurse or pharmacist immediately.

Too much TEVAGRASTIM may lead to neutrophil levels that are too high. Research has shown that doses almost 15 times greater than the most common dose do not immediately result in any harmful effects.

While you are using TEVAGRASTIM

Things you must do

Be alert for any signs or symptoms of infection.

There are many ways an infection may show itself.

You should watch for:

- fever (a temperature of 38.2°C or greater, or as your doctor suggests)
- chills
- rash
- sore throat
- diarrhoea
- ear ache
- difficult or painful breathing, coughing or wheezing.

If you develop any of these symptoms, go straight to your hospital.

If you are about to be started on any new medicine, tell your doctor, nurse and pharmacist that you are using Tevagrastim.

Tell any other doctors who treat you that you are taking this medicine.

If you become pregnant during treatment with TEVAGRASTIM, tell your doctor immediately.

Keep all of your doctor's appointments so that your health can be monitored.

Treatment with TEVAGRASTIM leads to changes in the numbers of certain blood cells. Your doctor may order blood tests to check the levels of infection-fighting neutrophils and other blood cells.

Blood tests may also be undertaken after you have completed your TEVAGRASTIM treatment until your blood cells have returned to normal levels.

Things you must not do

Do not use TEVAGRASTIM to treat any other complaint unless your doctor tells you to.

Do not give TEVAGRASTIM to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor as soon as possible if you have any problems while using TEVAGRASTIM, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, TEVAGRASTIM may have unwanted side effects. Some side effects may be serious and need medical attention. Other side effects are minor and are likely to be temporary. You may also experience side effects caused by other medicines you are taking at the same time as TEVAGRASTIM.

Do not be alarmed by this list of possible side effects.

You may not experience any of these side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, stop taking TEVAGRASTIM and go straight to hospital, as you may need urgent medical attention:

- rash over a large area of the body
- shortness of breath
- wheezing
- faintness, rapid pulse or sweating.

Severe allergic reactions to TEVAGRASTIM are very rare.

Tell your doctor immediately if you notice any of the following:

- pain in the upper left side of the abdomen
- left shoulder pain
- dizziness.

The above list includes serious side effects that may require medical attention.

Tell your doctor if you notice any of the following and they worry you.

Some of these are known side effects of chemotherapy and may not be related to TEVAGRASTIM:

- temporary bone pain, such as in the lower back or in the long bones of the arms or legs. This pain is usually relieved with non-prescription painkillers, like paracetamol. If you continue to have bone pain even after having taken this form of pain relief, you should speak to your doctor, as you may need a prescription medication.
- abdominal discomfort
- bleeding or bruising more than usual, severe nose bleeds, reddish or purplish blotches under the skin
- blood in the urine
- cough, breathlessness

- diarrhoea
- hair loss
- headache
- joint pain or worsening of existing arthritis
- muscle pain
- redness, swelling or itching at the site of injection
- skin disorders - worsening of existing symptoms
- skin rash or red, itchy spots
- sore mouth, mouth ulcers
- tiredness, looking pale.

Tell your doctor if you notice anything that worries you or that is making you feel unwell, even if it is not on this list.

Other side effects not listed above may occur in some people.

After using it

Storage

Keep TEVAGRASTIM in a refrigerator at a temperature of 2-8°C.

Keep TEVAGRASTIM in its carton protected from light.

Keep TEVAGRASTIM out of reach of children.

Disposal

Once you have injected TEVAGRASTIM, do not put the needle cover back on the used syringe. Put the used syringe into an approved, puncture-resistant, sharps container.

Dispose of the full puncture-resistant sharps container as instructed by your doctor, nurse or pharmacist.

Never put used syringes into your normal household rubbish bin.

Product description

What it looks like

TEVAGRASTIM is a clear, colourless solution and is supplied as ready to use syringes in packs of 1's, 5's and 10's.

The following strengths are available:

- 300 micrograms of filgrastim in a volume of 0.5 mL, in a syringe
- 480 micrograms of filgrastim in a volume of 0.8 mL, in a syringe.

Ingredients

The active ingredient in TEVAGRASTIM is filgrastim. Other ingredients are:

- Glacial acetic acid
- Polysorbate 80
- Sodium hydroxide
- Sorbitol
- Water for injections.

TEVAGRASTIM does not contain lactose, gluten, tartrazine or any other azo dyes.

Sponsor

TEVAGRASTIM is supplied in Australia by:

Teva Pharma Australia Pty Ltd

Level 2, 37 Epping Rd

Macquarie Park

NSW 2113

Telephone: 1800 288382

Australian Registration Numbers:

TEVAGRASTIM 300 mcg/0.5 mL syringe

AUST R 163675

TEVAGRASTIM 480 mcg/0.8 mL syringe

AUST R 163677.