

Consumer Medicine Information

Ziextenzo[®]

pegfilgrastim

6 mg of pegfilgrastim in 0.6 mL (10 mg/mL) solution for injection

What is in this leaflet

This leaflet answers some common questions about ZIEXTENZO.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZIEXTENZO against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ZIEXTENZO is used for

ZIEXTENZO solution for injection contains the active ingredient pegfilgrastim.

Using gene technology, pegfilgrastim is produced in a specific type of bacteria, called *E. coli*.

Pegfilgrastim is a long-acting form of recombinant human Granulocyte Colony Stimulating Factor (G-CSF). G-CSF is produced by the body in the bone marrow and assists in the production of neutrophils, which are a type of white blood cell. Neutrophils defend the body against infection by destroying bacteria in the blood.

ZIEXTENZO also helps neutrophils to be more effective.

Some chemotherapy medicines will reduce the number of neutrophils in your body. Although ZIEXTENZO is not a treatment for cancer, it is used following chemotherapy to increase the number of neutrophils. This will reduce your chance of developing infections that might require treatment with antibiotics and/or hospital stays. ZIEXTENZO may also help to keep your chemotherapy treatment on schedule.

ZIEXTENZO does not cure the underlying illness but it is an important supportive therapy.

Your doctor, however, may have prescribed ZIEXTENZO for another purpose.

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

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

Before you use ZIEXTENZO

When you must not use it

Do not use ZIEXTENZO if:

1. **you have previously used pegfilgrastim (ZIEXTENZO or NEULASTIM®) or filgrastim (NEUPOGEN® or ZARZIO®) and have had an allergic reaction to pegfilgrastim, filgrastim or any ingredients listed at the end of this leaflet**
2. **you have had an allergic reaction to medicines or other products that are produced by gene technology using the bacteria *E. coli***
3. **you are currently receiving chemotherapy or radiotherapy**
4. **you have received chemotherapy within the last 24 hours**
This is because the chemotherapy medicine may stop ZIEXTENZO from increasing the number of infection-fighting neutrophils.
5. **the package is torn or shows signs of tampering**
6. **the expiry date printed on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.
7. **the medicine has been left out of the refrigerator for more than 3 days.**

If you are not sure if you should be using ZIEXTENZO, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if:

1. **you have allergies to any other medicines or any other substances such as foods, preservatives or dyes**
2. **you are pregnant or plan to become pregnant**
Your doctor will discuss the possible risks and benefits of using ZIEXTENZO during pregnancy.
3. **you are breast-feeding or plan to breast-feed**
Your doctor will discuss the possible risks and benefits of using ZIEXTENZO while breast-feeding.
4. **you have any other health problems, especially the following:**
 - a medical condition affecting the bone marrow or blood
 - a family history of a genetic disorder called acute myeloid leukemia (AML), with cytogenetics t(15;17)
 - sickle cell disease [an inherited disease in which red blood cells are sickle (curved or tapered shaped)]
 - previous problems with your kidneys, liver, heart or other organs
 - previous radiotherapy or chemotherapy treatment for cancer
 - any infections, cancers or tumours.

If you have not told your doctor about any of the above, do so before you start to use ZIEXTENZO.

Your doctor will decide whether it is safe for you to use ZIEXTENZO.

Taking other medicines

Tell your doctor if you are taking any other medicines, particularly those which may affect the blood. Tell your doctor about any medicines or herbal remedies that you have bought from a pharmacy, supermarket or health foodshop.

Some medicines may interfere with ZIEXTENZO. These medicines include some chemotherapy medicines, such as fluorouracil, methotrexate and sulfanilamide.

These medicines may be affected by ZIEXTENZO or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using ZIEXTENZO.

Ask your doctor or pharmacist if you are not sure about other medicines you are taking.

How to use ZIEXTENZO

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

They may differ from the information contained in this leaflet.

ZIEXTENZO can be administered by a doctor, nurse or by patients themselves.

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

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

How much to inject

Use ZIEXTENZO exactly as your doctor has prescribed.

The usual dose is one subcutaneous injection.

When to inject

ZIEXTENZO should be injected 24 hours after the end of each chemotherapy cycle. Your doctor will tell you when to begin your treatment and when to stop

If you forget your injection

If you miss your scheduled dose, tell your doctor, nurse or pharmacist as soon as possible about your missed dose.

In case of an overdose

Immediately telephone your doctor, or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to your nearest Accident and Emergency Centre if you think you or anyone else may have had too much ZIEXTENZO. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using ZIEXTENZO

Things you must do

Tell all doctors, nurses and pharmacists who are treating you that you are using ZIEXTENZO.

Tell your doctor if you become pregnant while using ZIEXTENZO.

Be alert for any signs or symptoms of infection.

You should watch out for fever (your body temperature is raised above normal i.e. 37.6°C, or as

advised by your doctor), chills, rash, sore throat, diarrhoea, ear ache, difficult or painful breathing, coughing or wheezing.

If you develop any of these symptoms, see your doctor immediately or go to your nearest Accident and Emergency Centre.

Blood tests

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

Your doctor may arrange for blood tests to check the levels of infection-fighting neutrophils and other blood cells.

Things you must not do

Do not stop taking ZIEXTENZO or change the dose without first checking with your doctor.

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

Do not use ZIEXTENZO to treat other complaints unless your doctor says to.

Do not take other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ZIEXTENZO, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, ZIEXTENZO 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 ZIEXTENZO.

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

You may not experience any of them.

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

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 ZIEXTENZO:

- bone pain. *This pain is usually relieved with non-prescription painkillers, like paracetamol. If you continue to have bone pain even after taking this form of pain relief, you should speak to your doctor, as you may need a prescription medicine.*
- joint pain, muscle pain, pain in the chest area
- headache
- nausea (feeling sick) and/or vomiting
- skin rash or red, itchy or sore spots
- pain at the site of injection

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

- blood in urine
- fever and painful skin lesions most commonly on your arms, legs and sometimes on your face and neck
- swelling of the hands, legs, ankles, feet or any other part of the body
- left shoulder pain
- pain in the upper left side of the abdomen
- tiredness, shortness of breath, easy bleeding and frequent infections.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- coughing up blood, bleeding from the lung
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- swelling of your stomach-area (abdomen) and feeling of fullness
- swelling or puffiness
- less frequent urination
- faintness, rapid pulse, sweating, dizziness.

These may be serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in this list.

After using ZIEXTENZO

Storage

Keep your ZIEXTENZO in the original container, protected from light, until it is time to use it.

Keep ZIEXTENZO in the refrigerator where the temperature stays between 2°C and 8°C.

Exposure to room temperature (up to 35 °C) for a maximum single period of up to 120 hours will not harm ZIEXTENZO. Ziextenzo left at room temperature for more than 120 hours should be discarded.

Do not freeze.

Freezing should be avoided. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect the stability of Ziextenzo. If frozen a second time, ZIEXTENZO should be discarded.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep ZIEXTENZO where young children cannot reach it.

Disposal

Discard used syringe and needle into an approved puncture-resistant sharps container and keep it out of the reach of children.

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

Never put the used syringes into your normal household rubbish bin.

If your doctor tells you to stop using ZIEXTENZO, or it has passed its expiry date, ask your pharmacist what to do with any ZIEXTENZO that is left over.

Product Description

Availability

ZIEXTENZO is supplied as a solution for injection in a single-use pre-filled syringe with an injection needle and a needle guard.

What it looks like

ZIEXTENZO is a clear, colourless to slightly yellowish solution.

Ingredients

Active ingredient - pegfilgrastim

Inactive ingredients

ZIEXTENZO pre-filled syringes contain the inactive ingredients, acetic acid, sorbitol, polysorbate 20 sodium hydroxide (if necessary for pH adjustment) and water for injection.

Distributor

ZIEXTENZO is distributed in New Zealand by:

Novartis New Zealand Limited
Telephone: 0800 354 335

This leaflet was prepared on 12 December 2022.

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