

Ziextenzo®

pegfilgrastim

Consumer Medicine Information

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, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has prescribed Ziextenzo 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 Ziextenzo is used for

Ziextenzo is used following chemotherapy to help fight infection.

Some chemotherapy will reduce the number of neutrophils in your body. Although Ziextenzo is not a treatment for cancer, it does help the body to make new neutrophils. 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.

How it works

Ziextenzo is a long acting form of Recombinant Human Granulocyte

Colony Stimulating Factor or G-CSF. Using gene technology, Ziextenzo 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 the infections.

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 it

When you must not use it

Do not have Ziextenzo if you have an allergy to:

- any medicine containing pegfilgrastim or Filgrastim
- any of the ingredients listed at the end of this leaflet
- any medicines or products that are produced 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 Ziextenzo at the same time as your chemotherapy or radiotherapy.

Do not use Ziextenzo within 24 hours after you receive chemotherapy.

This is because the chemotherapy medicine may stop Ziextenzo from increasing the number of infection-fighting neutrophils.

Do not use Ziextenzo after the expiry date (EXP) printed on the pack

Do not use Ziextenzo if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should use 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
- any other substances, such as foods, preservatives or dyes.

2. you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having Ziextenzo during pregnancy.

3. you are breastfeeding or planning to breastfeed.

Your doctor will discuss the possible risks and benefits of having Ziextenzo during breastfeeding.

4. you have, or have had:

- a medical condition affecting the bone marrow or blood

- a family history of a genetic disorder
- sickle cell disease
- problems with your kidneys, liver, heart or other organs
- previous treatment for cancer
- any infections, cancers or tumours.

If you have not told your doctor about any of the above, tell them before you use Ziextenzo.

Taking other medicines

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

How to use it

Ziextenzo is given by injection, into the tissues just below the skin. This is called a subcutaneous injection.

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 Ziextenzo injection at home.

Carefully follow all directions given to you by your doctor, pharmacist or nurse. They may differ from the information in this leaflet.

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

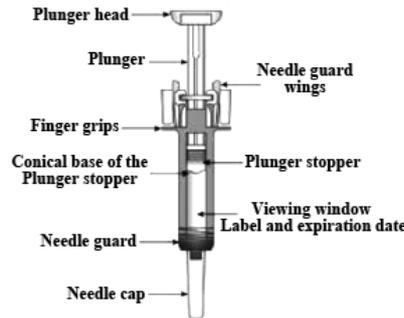
How to inject Ziextenzo using a pre-filled syringe with an automatic needle guard

To help avoid possible infections and to ensure that you use the

medicine correctly, it is important that you follow these instructions.

Read ALL the way through these instructions before injecting. It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist. The carton contains ZIEXTENZO® pre-filled syringe individually sealed in a plastic blister.

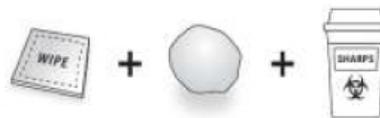
Your ZIEXTENZO® pre-filled syringe with needle guard



After the medicine has been injected, the needle guard will be activated to cover the needle. The needle guard is intended to protect healthcare professionals, caregivers and patients from accidental needle sticks after the injection.

What you additionally need for your injection:

- Alcohol swab.
- Cotton ball or gauze.
- Sharps disposal container.



Important safety information

Caution: Keep the pre-filled syringe out of the sight and reach of children.

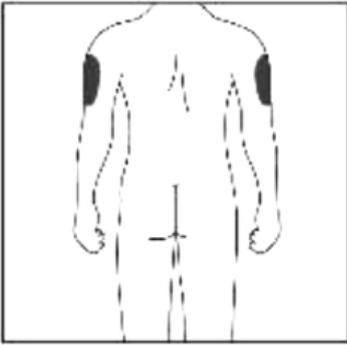
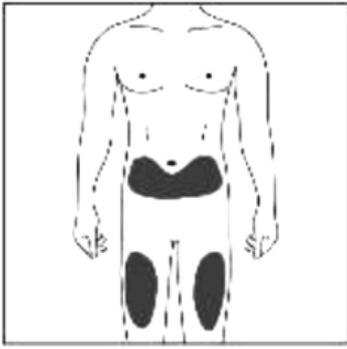
1. Do not open the carton until you are ready to use the pre-filled syringe.
2. Do not use the pre-filled syringe if the seal of the blister is broken, as it may not be safe for you to use.
3. Never leave the pre-filled syringe unattended where others might tamper with it.

4. Do not shake the pre-filled syringe.
5. Be careful not to touch the needle guard wings before use. By touching them, the needle guard may be activated too early.
6. Do not remove the needle cap until just before you give the injection.
7. The pre-filled syringe cannot be re-used. Dispose of the used pre-filled syringe immediately after use in a sharps container.

Storage of the ZIEXTENZO® pre-filled syringe

1. Store the blistered pre-filled syringe in its carton to protect it from light.
2. Store in the refrigerator between 2 °C and 8 °C. Do not freeze.
3. Prior to use, remove the pre-filled syringe from the refrigerator and allow ZIEXTENZO® to reach room temperature (up to a maximum of 25 °C) for approximately 15-30 minutes.
4. **Do not use** the pre-filled syringe after the expiry date which is stated on the carton or syringe label. If it has expired, return the entire pack to the pharmacy.

The injection site



The injection site is the place on the body where you are going to use the pre-filled syringe.

- The recommended site is the front of your thighs. You may also use the lower abdomen, but **not** the area 5 centimetres around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

If a caregiver is giving you the injection, the outer upper arms may also be used.

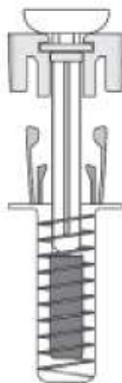
Preparing the ZIEXTENZO® pre-filled syringe ready for use

1. Take the carton containing the blistered pre-filled syringe out of the refrigerator and leave it **unopened** for approximately 15-30 minutes so that it reaches room temperature.
2. When you are ready to use the pre-filled syringe, open the blister and wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.
4. Remove the pre-filled syringe from the blister. Check to ensure

the plastic transparent needle guard is situated over the barrel of the glass syringe. If the transparent needle guard is covering the needle cap (as shown below) the syringe has been activated, **DO NOT** use this syringe and take a new syringe. The figure below shows a ready to use syringe.

5. Inspect the pre-filled syringe. The liquid should be clear. Its colour may vary from colourless to slightly yellowish. You may see a small air bubble in the liquid. This is normal. **Do not use** the pre-filled syringe if any other particulates and/or discolouration are observed.
6. **Do not use** if the syringe is broken or activated. Return the ZIEXTENZO® pre-filled syringe and the package to your pharmacy.

Device ACTIVATED – DO NOT USE



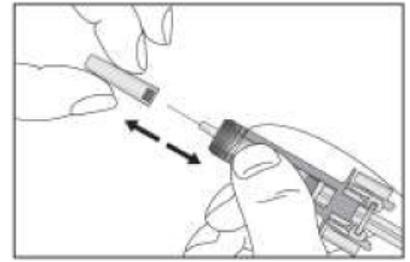
In this configuration the needle guard is ACTIVATED – DO NOT USE the pre-filled syringe

Device READY TO BE USED

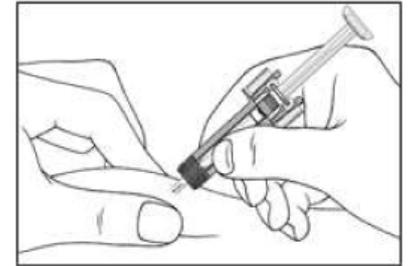


In this configuration the needle guard is NOT ACTIVATED and the pre-filled syringe is ready for use

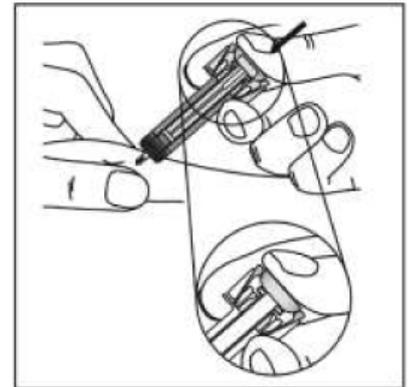
How to use the ZIEXTENZO® pre-filled syringe



Carefully pull the needle cap straight off. You may see a drop of liquid at the end of the needle. This is normal.

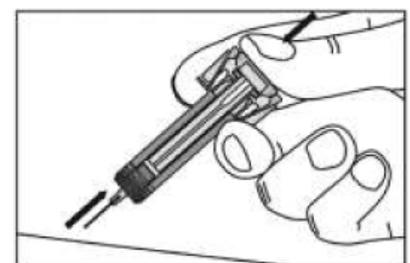


Gently pinch the skin at the injection site and insert the needle as shown. Push the needle all the way in to ensure that the medication can be fully administered.

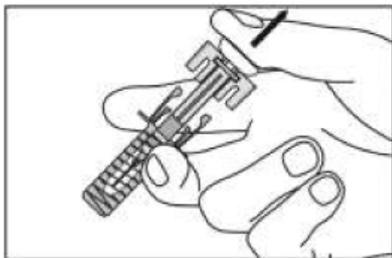


Holding the pre-filled syringe as shown, **slowly** depress the plunger **as far as it will go** so that the plunger head is completely between the needle guard wings.

Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds.



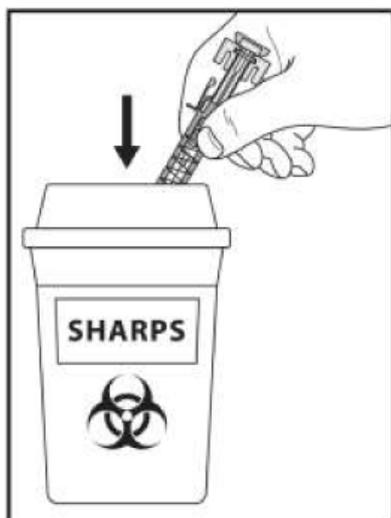
Keep the plunger fully depressed while you carefully pull the needle straight out from the injection site and let it go off your skin.



Slowly release the plunger and allow the syringe needle guard to automatically cover the exposed needle.

There may be a small amount of blood at the injection site. You can press a cotton ball or gauze onto the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

Disposal instructions



Dispose of the used syringe in a sharps container (closable, puncture resistant container).

Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Any unused product or waste material should be disposed of in accordance with local requirements.

Further information on use

How much to inject

The usual dose is one subcutaneous injection 24 hours after the end of each chemotherapy cycle.

When to inject

Use Ziextenzo 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, talk to your doctor, nurse or pharmacist as soon as possible.

If you inject too much (overdose)

If you inject more Ziextenzo than you need, talk to your doctor, nurse or pharmacist.

If you feel unwell in any way you talk to your doctor, nurse or pharmacist immediately.

While you are using it

Things you must do

Watch for any signs or symptoms of infection.

There are many ways an infection may show itself.

Symptoms of an infection include:

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

Go straight to your hospital if you develop any of these symptoms.

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor immediately if you become pregnant while taking this medicine.

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

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

Things you must not do

Do not use Ziextenzo to treat any other complaints unless your doctor tells you to.

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

Side effects

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

All medicines can have 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.

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

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

- 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 medicine.
- headache
- general aches and pains in joints and muscles
- reddish or purplish blotches under the skin
- injection site pain and redness of the skin at the injection site.

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

- pain in the upper left side of the stomach (abdomen)
- left shoulder pain
- dizziness
- fever and painful skin lesions most commonly on your arms, legs and sometimes on your face and neck
- blood in the urine
- tiredness, shortness of breath, easy bleeding and frequent infections.

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

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

- swelling or puffiness
- less frequent urination
- swelling of your stomach-area (abdomen) and feeling of fullness
- general feeling of tiredness.

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

Serious side effects are rare or uncommon.

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

- rash over a large area of the body, itching or hives
- shortness of breath, wheezing or difficulty breathing
- coughing up blood, bleeding from the lung
- swelling of the face, lips, tongue or other parts of the body
- faintness
- rapid pulse or sweating.

These are very serious side effects.

If you have them you may have had a serious allergic reaction to Ziextenzo. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that worries you or that is making you feel unwell.

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

After using it

Storage

Keep Ziextenzo in a refrigerator at a temperature of 2°C to 8°C.

Do not freeze.

Do not use Ziextenzo if you think it has been frozen. Exposure to room temperature of up to 3 days will not harm Ziextenzo.

Keep your medicine in its pack. Protect it from light.

Keep it where children cannot reach it.

Disposal

Once you have injected Ziextenzo, do not put the grey needle cap back on the used syringe.

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

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

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

Product description

What it looks like

Ziextenzo is a clear, colourless solution. It is supplied in a carton as a pre-filled syringe with an automatic needle guard.

Ingredients

Active ingredient: 6 mg pegfilgrastim

Inactive ingredients:

- acetic acid
- sorbitol
- polysorbate 20
- Water for Injections.

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

Sponsor

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Australian Registration Number:

Pre-filled syringe with automatic needle guard AUST R 308367

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