

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ziextenzo?

Ziextenzo contains the active ingredient pegfilgrastim. Ziextenzo is used to help fight infection, following chemotherapy.

For more information, see Section [1. Why am I using Ziextenzo?](#) in the full CMI.

2. What should I know before I use Ziextenzo?

Do not use if you have ever had an allergic reaction to pegfilgrastim, filgrastim or any of the ingredients listed at the end of the CMI or any medicines or products that are produced using the bacterial, *E. coli*.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Ziextenzo?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ziextenzo and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ziextenzo?

- 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 give yourself the injection at home.

More instructions can be found in Section [4. How do I use Ziextenzo?](#) in the full CMI.

5. What should I know while using Ziextenzo?

Things you should do	<ul style="list-style-type: none">• Watch for any signs or symptoms of infection.• Remind any doctor, dentist or pharmacist you visit that you are using Ziextenzo.• Tell your doctor immediately if you become pregnant while taking this medicine.• Be sure to keep all your doctor's appointments so your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine to treat any other complaints unless your doctor tells you to.• Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Ziextenzo affects you.

For more information, see Section [5. What should I know while using Ziextenzo?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the more common and serious side effects are included in full below in the CMI. Speak to your doctor if you have any of these side effects and they worry you. A very serious side effect is allergic reactions, the symptoms are:

- 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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ziextenzo®

Active ingredient(s): *pegfilgrastim*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ziextenzo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ziextenzo.**

Where to find information in this leaflet:

- [1. Why am I using Ziextenzo?](#)
- [2. What should I know before I use Ziextenzo?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Ziextenzo?](#)
- [5. What should I know while using Ziextenzo?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Ziextenzo?

Ziextenzo contains the active ingredient pegfilgrastim.

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.

Ziextenzo is used to help fight infection, following chemotherapy.

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.

2. What should I know before I use Ziextenzo?

Warnings

Do not use Ziextenzo if:

- you are allergic to pegfilgrastim, filgrastim or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to 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.

Check with your doctor if you:

- have or have had any other medical conditions, including:**
 - 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
 - allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition.**

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ziextenzo.

4. How do I use Ziextenzo?

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 much to take

- The usual dose is one subcutaneous injection 24 hours after the end of each chemotherapy cycle.
- Follow the instructions provided and use Ziextenzo until your doctor tells you to stop.

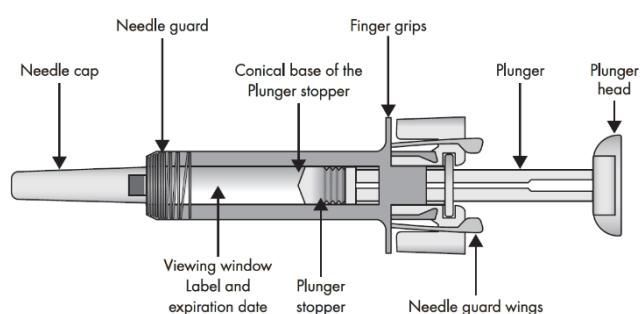
When to take Ziextenzo

- **Ziextenzo should be used 24 hours after the end of each chemotherapy cycle.**

How to take Ziextenzo

- 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 the pre-filled syringe individually sealed in a plastic blister.

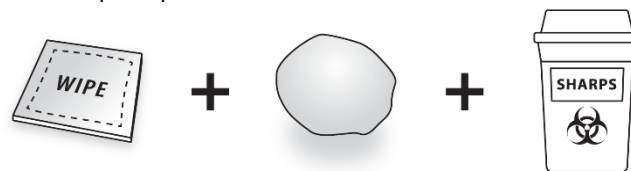
Your Ziextenzo pre-filled syringe with needle guard



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 stick injuries after the injection.

What you additionally need for your injection:

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



Important safety information

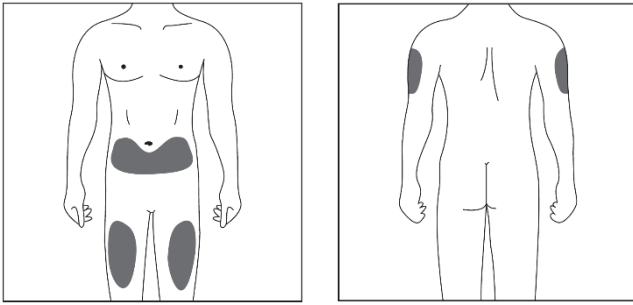
Caution: Keep the pre-filled syringe out of the sight and reach of children.

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. Do not use the pre-filled syringe if there is liquid in the blister. Do not use the pre-filled syringe if the needle cap is missing or not securely attached. In all these instances, return the entire product pack to the pharmacy.
4. Never leave the pre-filled syringe unattended where others might tamper with it.
5. Do not shake the pre-filled syringe.
6. Be careful not to touch the needle guard wings before use. By touching them, the needle guard may be activated too early.
7. Do not remove the needle cap until just before you give the injection.
8. The pre-filled syringe cannot be re-used. Dispose of the used syringe immediately after use in a sharps container.
9. Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap.

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 35 °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



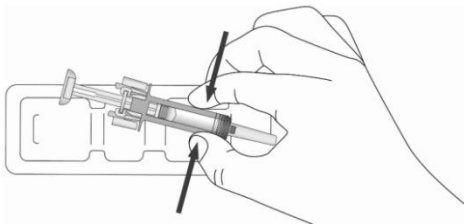
The injection site is the place on the body where you are going to use the pre-filled syringe.

- 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.

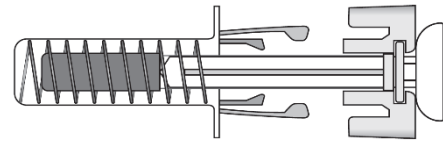
Preparing the Ziextenzo pre-filled syringe ready for use

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 by holding it in the middle as shown below. Do not grab the plunger. Do not grab the needle cap.



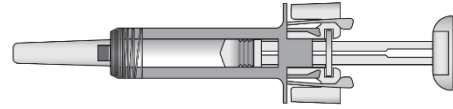
5. Check to ensure the plastic transparent needle guard is situated over the barrel of the glass syringe. If the transparent needle guard is covering the needle cap (as shown below) the syringe needle guard has been activated, **DO NOT** use this syringe and take a new syringe. The figure below shows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

Device ACTIVATED – DO NOT USE



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

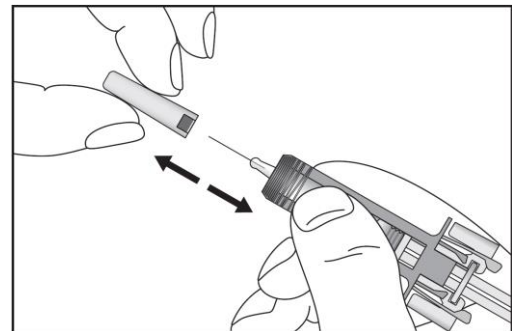
Device **READY TO BE USED**



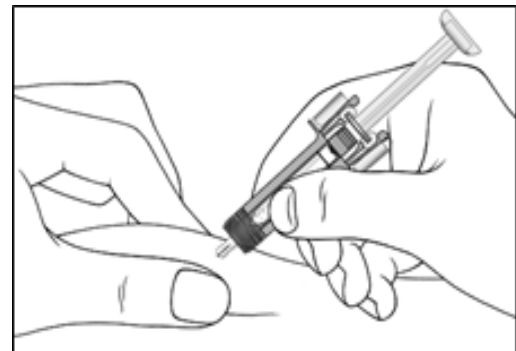
In this configuration the needle guard is **NOT ACTIVATED** and the pre-filled syringe is ready for use

6. 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 discoloration are observed.
7. **Do not use** if the syringe is broken or activated. Return the Ziextenzo pre-filled syringe and the package to your pharmacy.

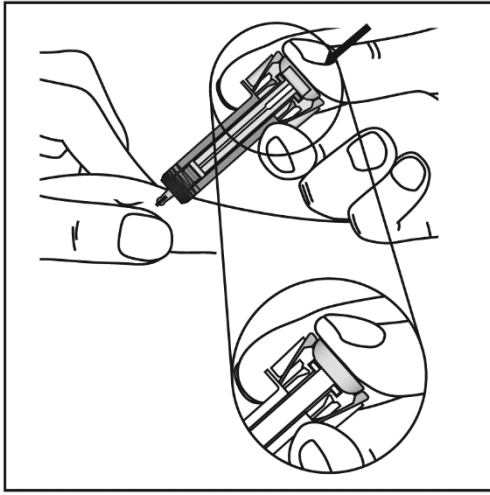
How to use the Ziextenzo pre-filled syringe



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

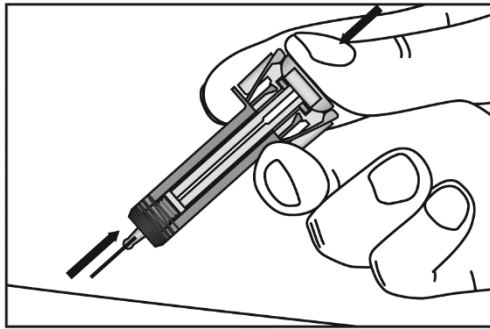


2. Gently pinch the skin at the injection site and insert the needle as shown. Push the needle all the way in to ensure that the medicine can be fully administered.

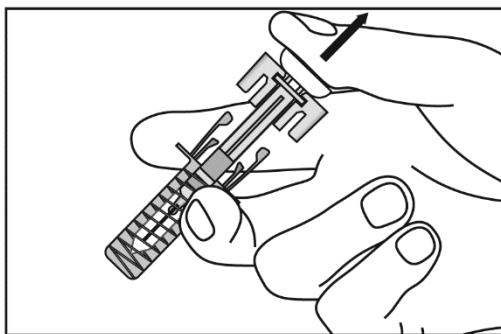


3. Holding the pre-filled syringe as shown, **slowly** depress the plunger **as far as it will go** so that the plunger head is completely between the needle guard wings.

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

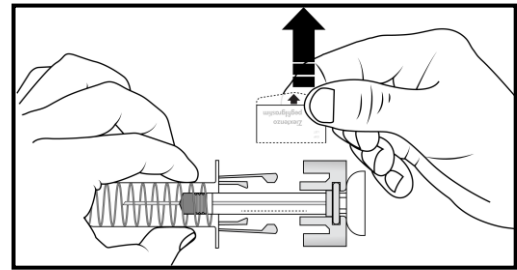


4. **Keep the plunger fully depressed** while you carefully pull the needle straight out from the injection site and let it go off your skin.



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

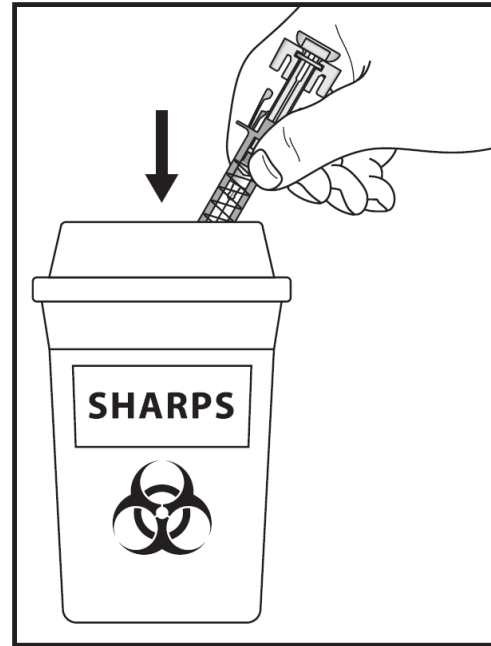
There may be a small amount of blood at the injection site. You can press a cotton ball or gauze onto the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.



6. **Healthcare providers only**

The trade name of the administered product should be clearly recorded in the patient file. Remove and save the pre-filled syringe label.

Turn the plunger to move the label into a position where you can remove the syringe label.



7. **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.

If you forget to use Ziextenzo

If you miss your scheduled dose, talk to your doctor, nurse or pharmacist as soon as possible.

If you use too much Ziextenzo

If you think that you have used too much Ziextenzo, you may need urgent medical attention.

You should immediately:

- phone the [Australian](#) Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Ziextenzo?

Things you should 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.

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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ziextenzo affects you.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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 young 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • pain in the upper left side of the stomach (abdomen) • left shoulder pain • dizziness • fever and painful skin lesions most commonly on your arms, 	<p>Tell your doctor as soon as possible or go straight to the Emergency Department at your nearest</p>

<ul style="list-style-type: none"> legs and sometimes on your face and neck • blood in the urine • tiredness, shortness of breath, easy bleeding and frequent infections. • swelling or puffiness • less frequent urination • swelling of your stomach-area (abdomen) and feeling of fullness • general feeling of tiredness. 	<p>hospital if you experience any of the following symptoms.</p>
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Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	<p>Stop taking the medicine and go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Ziextenzo contains

Active ingredient (main ingredient)	pegfilgrastim
Other ingredients (inactive ingredients)	acetic acid, sorbitol, polysorbate 20, Water for Injections.

Potential allergens	Ziextenzo does not contain lactose, gluten, tartrazine or any other azo dyes.
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Do not take this medicine if you are allergic to any of these ingredients.

What Ziextenzo looks like

Ziextenzo is a clear, colourless solution. It is supplied in a carton as a pre-filled syringe with an automatic needle guard. (Aust R 308367).

The syringe and needle guard do not contain natural rubber latex or any derivatives.

Who distributes Ziextenzo

Ziextenzo is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Ziextenzo is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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