

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 Terrosa?

Terrosa contains the active ingredient teriparatide. Terrosa is used to treat osteoporosis in women after menopause and in men. Osteoporosis is a disease that causes your bones to become thin and fragile. For more information, see [Section 1](#). Why am I using Terrosa? in the full CMI.

2. What should I know before I use Terrosa?

Do not use if you have ever had an allergic reaction to Terrosa or any of the ingredients listed at the end of the CMI.

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 Terrosa? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Terrosa 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 Terrosa?

- A dose of 80 microlitres containing 20 micrograms of Terrosa is given once a day by injection under the skin in the thigh or abdomen
- The dose is injected using a reusable Terrosa Pen that is supplied with the medicine for the first prescription.
- The cartridge must be used for multiple injections by ONE person only.

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

5. What should I know while using Terrosa?

Things you should do	<ul style="list-style-type: none"> • Before you start to use Terrosa, you will be required to sign your consent that you understand the 24 month lifetime limit for treatment. Keep a copy of the consent form as you may need to show it to your doctor or pharmacist. • Remind any doctor, dentist or pharmacist you visit that you are using Terrosa • Tell your doctor if you have high levels of calcium in the blood • Tell your doctor you suffer from kidney stones or you have kidney problems • Blood test for serum calcium, if needed, can be taken 16 hours after your last injection • Keep all your doctor's appointments • Write the date of your first injection as treatment duration is a total of 24 months only • Read the "Instructions for Use" on how to use the Terrosa Pen and the package insert before beginning therapy
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine unless your doctor has told you to • Do not use this medicine if you are pregnant or breastfeeding • Do not use this medicine if you have had metabolic bone disease (including Paget's disease of the bone or hyperparathyroidism) • Do not use this medicine if you have severe kidney disease
Driving or using machines	<ul style="list-style-type: none"> • Do not drive or use machines if you feel dizzy after injecting Terrosa.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol
Looking after your medicine	<ul style="list-style-type: none"> • Keep Terrosa in the fridge where the temperature is between 2°C to 8°C. Do not freeze. Discard the medicine if it has frozen • Do not transfer medicine to a syringe • Do not store Terrosa Pen with a needle attached. Use a new needle for each injection • Do not remove the cartridge from the pen after each use, it must remain in the pen during the whole 28-day treatment period • Return the loaded Terrosa Pen immediately to the fridge after each use • Discard the cartridge 28 days after first use, even if it still contains some unused solution • Do not discard the Terrosa Pen. You will need to use it for the duration of your treatment.

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

6. Are there any side effects?

The most common side effects are pain in a limb, feeling sick, headache, dizziness and discomfort around the area of the injection. Serious side effects include allergic reactions and increased calcium in your blood or urine leading to kidney stones. 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.

TERROSA®

Active ingredient(s): teriparatide (ter i PAR a tide) (rbe)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Terrosa. 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 Terrosa.

Where to find information in this leaflet:

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

1. Why am I using Terrosa?

Terrosa contains the active ingredient teriparatide. Teriparatide is a recombinant parathyroid hormone. It is used to make bones stronger and to reduce the risk of fractures by stimulating bone formation.

Terrosa is used to treat osteoporosis in women after menopause and in men. Osteoporosis is a disease that causes your bones to become thin and fragile. This disease is especially common in women after the menopause but can also occur in men. Osteoporosis is also common in patients receiving medicines called corticosteroids such as prednisone, cortisone.

2. What should I know before I use Terrosa?

Do not use Terrosa if:

- You have previously received teriparatide therapy for a total of 24 months. If you are not sure if you have previously received teriparatide therapy, speak to your doctor or pharmacist.
- You are allergic to teriparatide or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the 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; rash, itching or hives on the skin
- You have severe kidney disease.
- You have been diagnosed with Paget's disease of the bone (a disease with abnormal bone changes).
- You have unexplained high levels of alkaline phosphatase (ALP) in your blood. If you are not sure, ask your doctor.
- You have high levels of calcium in your blood (pre-existing hypercalcaemia). Signs and symptoms of high calcium may include continuous nausea, vomiting,

constipation, low energy or muscle weakness. Terrosa may cause an increase in the amount of calcium in your blood or urine.

- You have ever had bone cancer or if other cancers have spread (metastasised) to your bones.
- You have certain bone disorder other than osteoporosis (including hyperparathyroidism). If you have a bone condition, tell your doctor.
- You have had radiation therapy involving your bones.
- You are pregnant or breastfeeding.
- You are a child or a young adult who is still growing (open epiphyses).

Terrosa is a clear, colourless solution. Do not use Terrosa if there are solid particles in it or the solution is cloudy or coloured.

Warnings

In rats that were treated with teriparatide (rbe) for more than a quarter of their lifetime, teriparatide caused some rats to develop osteosarcoma, a bone cancer. The potential to cause osteosarcoma in rats was increased with higher doses and longer periods of treatment.

Osteosarcoma in humans is a serious but very rare cancer. Osteosarcoma occurs in about 4 out of every million people each year.

There is one report of osteosarcoma in a patient administered teriparatide (rbe) for 14 months. Due to the complex medical history, cause and effect between teriparatide (rbe) and osteosarcoma could not be established. At present, it is not known whether humans treated with teriparatide (rbe) would have an increased chance of getting osteosarcoma.

You should discuss any safety concerns you have about the use of teriparatide (rbe) with your doctor.

Check with your doctor if you:

- Have any other medical conditions.
- Take any medicines for any other condition.
- Suffer from kidney stones or have had kidney stones.
- Suffer from kidney problems (moderate renal impairment).
- Have low blood pressure (hypotension).
- Plan to become pregnant..

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?

Terrosa contains less than 1 mmol sodium (23 mg) in each dosage unit.

Some patients get dizzy or get a fast heartbeat after the first few doses of Terrosa. For the first doses, inject Terrosa in a

place where you can sit or lie down right away if you get dizzy.

Before inserting a cartridge in the reusable Terrosa Pen (PEN) write down the batch (Lot) number of the cartridge and the first injection date on a calendar. The date of first injection should also be recorded on the outer carton of Terrosa cartridge (see [Section 4](#)) How do I use Terrosa)).

Pregnancy and breastfeeding

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

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

Do not use Terrosa if you are pregnant or breastfeeding.

You should use effective methods of contraception during use of Terrosa if you are a woman of childbearing potential.

You should stop using Terrosa If you become pregnant.

Children and adolescents

Terrosa should not be used in children and adolescents (aged less than 18 years).

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.

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

For example

- digoxin or digitalis, a medicine used to treat heart disease may interact with teriparatide.
- diuretics (medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced, such as hydrochlorothiazide and frusemide).
- anti-coagulants (medicines used to prevent blood clotting).

You can take calcium or vitamin D supplements (or both) while you are using your medicine. You should discuss with your doctor how much calcium and vitamin D to take each day.

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

4. How do I use Terrosa?

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- To help you remember to take your medicine, inject it at about the same time each day.
- Inject Terrosa each day for as long as your doctor prescribes it for you.

- Your doctor may advise you to take Terrosa with calcium or vitamin D supplements (or both).
- Terrosa cartridges are meant to be used only with the Terrosa Pen, which is a reusable, multidose delivery system.
- Use a new injection needle for each injection to prevent contamination.
- Never store your pen with the needle attached.
- Never share your pen with others.
- Do not use your pen to inject any other medicine (e.g. insulin). The pen is designed for use with Terrosa cartridge only.
- Do not transfer the medicine into a syringe.
- Check the expiry date (EXP) on the cartridge label and that the solution is clear before inserting the cartridge into the pen.
- Make sure there are at least 28 days left before the expiry date.
- Write down the Lot number (Lot) of the cartridge and the date of first injection on a calendar or diary.
- Discard the cartridge ONLY after 28 days of first use, even if you have not injected all of the contents.
- Do not discard the Terrosa Pen. Keep the pen for the duration of your treatment.

How much to use

- A dose of 80 microlitres (20 micrograms) is given once a day by injection under the skin in the thigh or abdomen.
- Follow the Instructions for Use provided and use Terrosa until your doctor tells you to stop.
- You should not receive more than one teriparatide treatment course of 24 months over your lifetime.

You will be required to sign your consent that you understand the 24 month lifetime limit.

When to use Terrosa

- An injection of Terrosa is given once a day.
- You can use Terrosa with or without food.

How to inject Terrosa

Before first use, insert the cartridge into the Terrosa Pen. For correct use of this medicine, it is very important to closely follow the detailed Instructions for Use provided with the pen.

If you forget to use Terrosa

Terrosa should be used regularly at the same time each day. If you forget to use Terrosa at the usual time, use it as soon as you remember.

If it is almost time for your next injection, skip the dose you missed and use your next dose when you are meant to.

Do not use a double dose to make up for the dose you missed. Do not use more than one injection in the same day.

If you use too much Terrosa

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.

The expected effects of overdose include nausea, vomiting, dizziness and headache.

5. What should I know while using Terrosa?

Things you should do

Follow the instructions provided with the Terrosa Pen on how to prepare and use your Terrosa injection. If the instructions are not followed, there are risks of incorrect medication, inaccurate dosage, disease transmission and infection.

Needles are not included with the pen. You may use Becton Dickinson or Ypsomed's 29 to 31-gauge needles. Pen needles from other manufacturers can be used according to their stated compatibility details.

If you do not understand the Instruction for Use ask your doctor or pharmacist for help.

You should have your Terrosa injection shortly after taking it out of the fridge. Return immediately to the fridge after use.

Tell your doctor if you are about to have a blood test that you are taking Terrosa. This medicine can cause temporary increase in blood calcium level. If blood samples are taken, this needs to be done at least 16 hours after your last Terrosa injection.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Terrosa.

Keep all your doctor's appointments so that your progress can be checked. Your doctor may do some tests (like bone mineral density test and blood tests) to make sure the medicine is working and to prevent unwanted side effects.

Keep using your medicine even if you feel well.

Call your doctor straight away if you:

- have any health concerns.
- become pregnant while using this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Terrosa.

Things you should not do

Do not stop using Terrosa before discussing it with your doctor.

Driving or using machines

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

Some patients may feel dizzy after injecting Terrosa. If you feel dizzy you should not drive or use machines until you feel better.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

- **Before inserting** the cartridge in the Terrosa Pen keep the cartridge in its outer carton in the fridge where the temperature is 2°C to 8°C. Do not freeze.
- **Without** the cartridge inserted the Terrosa Pen can be stored in the fridge or at room temperature.
- **With** the cartridge inserted the Terrosa Pen must be stored in the fridge where the temperature is 2°C to 8°C. Do not freeze.
- You can use Terrosa for up to 28 days after the first injection.
- Do not place the cartridge or pen with the cartridge inserted close to the ice compartment of your fridge in order to prevent freezing. Do not use Terrosa if it is or has been frozen.

How to look after your Terrosa Pen

- Handle your pen with care. Do not drop your pen. Avoid knocking it against hard surfaces. Protect it from water, dust and moisture.
- Use a damp cloth to clean your Terrosa Pen. Do not use alcohol, other solvents or cleaning agents. Never put your pen in water as this could damage the pen.
- Do not use your pen if it is damaged or if you have doubts it is not working properly.
- Do not store your pen with a needle attached as this may cause air bubbles to form in the cartridge.
- Do not remove the cartridge from the pen after each use. The cartridge must only be removed after 28 days from first use and replaced each time with a new cartridge until the end of your treatment as discussed with your doctor.

Keep the Terrosa cartridge, pen and needles where young children cannot reach them.

When to discard your medicine and pen

- Each cartridge should be properly disposed of after 28 days from the first use even if it is not completely empty. Each Terrosa cartridge should not be used for more than 28 days.

- Always remove the needle and cartridge from the pen and dispose of them separately.
- Terrosa Pen should be properly disposed of after 2 years of use or when your treatment is completed.

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 which is found on the carton and the cartridge.

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"> • Feeling sick (nausea) • Feeling faint • Dizziness • Tiredness • Loss of energy • Muscle cramps in the leg or back • Pain in the muscles or joints • Headache • Pain • Rash • Itching and hives • Increased sweating • Sleeplessness • Discomfort or pain around injection site such as redness of skin, swelling, itching, bruising or minor bleeding • Pain in neck • Vomiting • Constipation • Diarrhoea • Disorder of the digestive system • Tooth disorder • Increase in blood levels of uric acid • Rhinitis • Increased coughing • Pharyngitis • Anaemia (low level of red blood cells; this can only be found when the doctor does tests from time to time to check your progress) 	<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"> • Kidney stones and increase in blood calcium • Strong pain in the muscles and pain in the joints. Some patients have had severe back cramps or pain which led to admission into hospital. • Swelling in face, mouth, hands, feet, legs or other parts of your body (including breathlessness, chest pain, and anaphylaxis a serious allergic reaction) • Pneumonia • Depression • Confusion • Changes in heart rate • Breathlessness • Chest pain • High blood pressure • Kidney impairment or failure 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these 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. 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 Terrosa contains

Active ingredient (ingredient that makes the medicine work)	Teriparatide
Other ingredients (inactive ingredients)	Glacial acetic acid Mannitol Metacresol Sodium acetate trihydrate Hydrochloric acid Sodium hydroxide Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Terrosa looks like

Terrosa is a clear, colourless solution.

The 2.4 mL of solution which is enough for 28 doses is supplied in a 3mL cartridge.

Terrosa is available in pack(s) of 1 cartridge or 3 cartridges. Terrosa cartridge must be used with a TERROSA PEN, a reusable autoinjector device.

Keep the TERROSA PEN for the duration of your treatment as discussed with your doctor.

The Australian registration numbers AUST R 326885.

Not all pack may be marketed.

Who distributes Terrosa?

Gedeon Richter Australia Pty Ltd
Suite 902/15 Blue Street
NORTH SYDNEY
NSW 2060
Phone: 1300 GEDEON (1300 433 366)

® = Registered Trademark

This leaflet was prepared in May 2022.