

FORTEO®

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 FORTEO?

FORTEO contains the active ingredient teriparatide. FORTEO is used in adults to treat osteoporosis in women after menopause and in men when other medicines are unsuitable or when there is a high risk of fractures. It is also used to treat women and men who have developed osteoporosis as a result of taking corticosteroids.

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

2. What should I know before I use FORTEO?

Do not use if you have previously been treated with teriparatide for a total of 24 months or have ever had an allergic reaction to teriparatide 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 FORTEO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FORTEO 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 FORTEO?

- The usual dose is 20 mcg given once a day.
- FORTEO is given by injection under the skin (subcutaneous) into the thigh or abdomen.

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

5. What should I know while using FORTEO?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using FORTEO.● If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine suddenly without checking with your doctor.● Do not give or share your medicine with anyone else, even if they have the same condition as you and you have changed the needle.
Driving or using machines	<ul style="list-style-type: none">● Be careful before you drive or use any machines or tools until

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are using FORTEO. ● If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.
	<p>you know how FORTEO affects you.</p> <ul style="list-style-type: none"> ● Some patients may feel dizzy or experience light-headedness on standing up after injecting FORTEO. If you feel dizzy or light-headed you should not drive or use machines until you feel better.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep your FORTEO pen in the refrigerator where the temperature stays between 2°C to 8°C. Do not allow your FORTEO pen to freeze. Do not use FORTEO if it has been frozen.

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are using FORTEO. ● If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.
	<ul style="list-style-type: none"> ● You should use a new needle for each injection. Do not store your pen with the needle attached.

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

6. Are there any side effects?

The most common side effects are discomfort around the area of injection, such as redness of the skin, pain, swelling, itching, bruising or minor bleeding, feeling sick (nausea), leg cramps, muscle spasms, weakness and lack of energy. The serious side effects include allergic reactions such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips or tongue, rash, itching or hives on the skin, chest pain or discomfort, reduced urination due to reduced kidney

function or kidney failure, pneumonia, shortness of breath and serious back spasms. 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.

FORTEO®

Active ingredient(s): *teriparatide (rbe)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FORTEO. **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 FORTEO.**

Where to find information in this leaflet:

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

1. Why am I using FORTEO?

FORTEO contains the active ingredient teriparatide (rbe). FORTEO is recombinant parathyroid hormone. It works by activating cells in the bone to form new bone, making bones stronger and reducing the risk of fractures (breaks).

FORTEO is used in adults to treat:

- **osteoporosis in women after menopause**
- **osteoporosis in men when other medicines are unsuitable or when there is a high risk of fractures**
- **osteoporosis due to corticosteroid use in women and men who are at high risk of fractures.**

Osteoporosis is a disease which causes bones to become thin and fragile, gradually making them weaker, more brittle and likely to break. This disease is especially common in women after the menopause but can also occur in men. Osteoporosis is also common in patients receiving corticosteroids (such as prednisone, cortisone).

Although it may have no symptoms at first, osteoporosis makes you more likely to break bones, especially in your spine, hips and wrists and may cause back pain, loss of height and a curved back.

Using this medicine each day will protect your bones by making them stronger and your risk of fracture will be reduced.

2. What should I know before I use FORTEO?

Warnings

In rats that were treated with FORTEO 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 FORTEO for 14 months. Due to the complex medical history, cause and effect between FORTEO and osteosarcoma could not be established. At present, it is not known whether humans treated with FORTEO would have an increased chance of getting osteosarcoma.

You should discuss any safety concerns you have about the use of FORTEO with your doctor.

Do not use FORTEO if you:

- have previously been treated with teriparatide for a total of 24 months.
- 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.
- are pregnant or breastfeeding.

- have high calcium levels in the blood (hypercalcaemia).
- have severe kidney disease (severe renal impairment).
- have ever had metabolic bone disease other than primary osteoporosis or glucocorticoid-induced osteoporosis (osteoporosis caused by corticosteroids). This includes Paget's disease of the bone (disease with abnormal bone changes) or hyperparathyroidism (increase in parathyroid hormone).
- have unexplained high levels of a liver enzyme called alkaline phosphatase (ALP) in the blood.
- have ever had external beam or implant radiation therapy to the skeleton (radiation therapy).
- have ever had bone cancer or other cancers that have spread (metastasised) to your bones.
- have bones that have not finished growing (open epiphyses, the rounded portion of the bone).

This medicine should not be used in children or in growing adults.

Check with your doctor if you:

- **have previously received teriparatide therapy for a total of 24 months. Treatment with FORTEO should not exceed 24 months in a lifetime. This total of 24 months therapy may have been made up of several shorter courses of FORTEO. If you are not sure if you have previously received FORTEO, speak to your doctor or pharmacist. You will be required to sign your consent that you understand the 24 month lifetime limit. Keep this**

consent form as you may need to show this to your doctor in the future. Your pharmacist may also ask to see your consent form.

- have any other medical conditions like:
 - high calcium levels in the blood (pre-existing hypercalcaemia). FORTEO may cause an increase in the amount of calcium in your blood or urine. Signs and symptoms of high calcium in the blood may include:
 - continuing nausea,
 - vomiting,
 - constipation,
 - low energy,
 - muscle weakness.
 - if you suffer from kidney stones or have a history of kidney stones
 - low blood pressure (hypotension)
 - kidney disease (moderate renal impairment)
 - have allergies to any other medicines, foods, preservatives or dyes
 - narrowing of the spine that causes pain, numbness and weakness (spinal stenosis)
 - take any medicines for any other condition.

If you are not sure whether you should start using this medicine, talk to your doctor.

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.

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

FORTEO should not be used if you are pregnant or breastfeeding. If you are a woman of childbearing potential, you should use effective methods of contraception during treatment with FORTEO.

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 and FORTEO may interfere with each other. These include:

- 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.
- Digoxin, a medicine used to treat heart failure.

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

You can take calcium or vitamin D supplements (or both) while you are using FORTEO if your diet does not provide enough. You should discuss with your doctor how much calcium and vitamin D to take each day.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using FORTEO.

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

4. How do I use FORTEO?

Carefully follow all directions given to you by your doctor or healthcare professional.

They may differ from the information contained in this leaflet. Read the user manual for instructions on how to use the pen. Needles are not included with the pen. You can use Becton Dickinson and Company's pen needles or their equivalent with the pen.

If you do not understand the user manual, ask your doctor or healthcare professional for help.

How much to use

- The usual dose is 20 mcg given once a day.
- Follow the instructions provided by your doctor and use FORTEO until your doctor tells you to stop.

When to use FORTEO

- You can take FORTEO at any time of day.
- To help you remember, take your medicine at about the same time each day.

How to inject FORTEO

- FORTEO is given by injection under the skin (subcutaneous) into the thigh or abdomen.
- You should always use a new needle for each injection.
- Your healthcare professional (doctor or nurse) should teach you how to use the FORTEO pen (multidose prefilled delivery device).
- It is a good idea to refer to the user manual each time you inject this medicine.

How long to use FORTEO

- The total duration of treatment with FORTEO should not exceed 24 months.
- Continue using your medicine for as long as your doctor tells you.
- This medicine helps to control your condition but does not cure it. It is important to keep using your medicine even if you feel well.

If you forget to use FORTEO

If you miss your dose at the usual time, have it as soon as possible on that day. Do not have more than one injection on the same day. **Do not take a double dose to make up for the dose you missed.**

This may increase the chance of you having an unwanted side effect.

If you are not sure what to do, ask your doctor or healthcare professional.

If you have trouble remembering to use your medicine, ask your healthcare professional for some hints.

If you use too much FORTEO

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

Symptoms of an overdose may include:

- high blood serum calcium levels
- dizziness or light-headedness on standing up
- nausea
- vomiting
- dizziness
- headache
- feeling weak or tired

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.

5. What should I know while using FORTEO?

Things you should do

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are using this medicine.

This medicine can cause small, temporary increases in blood calcium levels. If blood samples are taken, this needs to be done at least 16 hours after the last injection.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (like bone mineral density tests and blood tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

- become pregnant while using this medicine.

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

Things you should not do

- Do not stop using this medicine suddenly without checking with your doctor.
- Do not use FORTEO to treat any other complaints unless your doctor tells you to.
- Do not give or share your medicine with anyone else, even if they have the same condition as you and you have changed the needle.

Driving or using machines

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

This medicine is not expected to affect your ability to drive a car or use machinery.

Some patients may feel dizzy or experience light-headedness on standing up after injecting FORTEO. If you feel dizzy or light-headed you should not drive or use machines until you feel better.

Looking after your medicine

- Keep your FORTEO pen in the refrigerator where the temperature stays between 2°C to 8°C.

- Do not allow your FORTEO pen to freeze. Do not use FORTEO if it is or has been frozen.
- You should have your FORTEO injection shortly after you take the pen out of the refrigerator as described in the user manual. Put the pen back into the refrigerator immediately after you have used it.
- Do not use the FORTEO pen 28 days after the first injection, even if it has been stored in the refrigerator.
- Do not store your pen with the needle attached. If you do this, it may allow solution to leak from the pen and air bubbles to form in the cartridge.
- FORTEO is a clear and colourless liquid. Do not use if solid particles appear or if the solution is cloudy or coloured.

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

Keep it where young children cannot reach it.

When to discard your medicine

Each FORTEO pen can be used for up to 28 days after the first injection. After the 28-day use period, discard the pen even if it contains some unused solution.

Empty FORTEO pens and any needles should be disposed of in a 'sharps' container or similar puncture proof container composed of hard plastic or glass.

Ask your doctor or nurse where you can dispose of the container once it is full.

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 FORTEO after the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

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
<p>Body as a whole:</p> <ul style="list-style-type: none">• pain• headache• weakness and lack of energy• neck pain• problems with teeth• leg cramps	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● muscle spasms in the leg or back sometimes shortly after the first dose ● joint pain ● muscle pain <p>Injection site related:</p> <ul style="list-style-type: none"> ● discomfort around the area of injection, such as <ul style="list-style-type: none"> ○ redness of the skin, ○ pain, ○ swelling, ○ itching ○ bruising or minor bleeding at the injection site. <p>Heart related:</p> <ul style="list-style-type: none"> ● increased blood pressure ● feeling faint <p>Stomach related:</p> <ul style="list-style-type: none"> ● feeling sick (nausea) ● constipation ● diarrhoea 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● heartburn and indigestion ● vomiting ● disorder of the digestion system <p>Nervous system related:</p> <ul style="list-style-type: none"> ● dizziness (light-headedness) after injection. If you become dizzy (light-headed) after your injection, you should sit or lie down until you feel better. If you do not feel better, you should call a doctor before you continue treatment ● low mood, lack of interest in activities (depression) ● trouble sleeping (insomnia) ● feeling of spinning (vertigo) <p>Respiratory system related:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● stuffy, running nose, sneezing ● increased coughing ● sore throat <p>Skin related:</p> <ul style="list-style-type: none"> ● rash ● sweating 	

Serious side effects

Serious side effects	What to do
<p>Allergic reactions:</p> <p>Symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none"> ● shortness of breath, ● wheezing or difficulty breathing, ● swelling of the face, lips or tongue, ● rash, itching or hives on the skin and ● chest pain <p>Heart related:</p>	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> ● chest pain or discomfort <p>Kidney related:</p> <ul style="list-style-type: none"> ● reduced urination due to reduced kidney function or kidney failure <p>Respiratory system related:</p> <ul style="list-style-type: none"> ● pneumonia (inflammation in the lungs) that can cause a cough, shortness of breath and chest pain ● shortness of breath <p>Muscle related:</p> <ul style="list-style-type: none"> ● serious back spasms 	

Other changes you may not be aware of:

- high amount of uric acid in the blood
- high calcium levels in the blood
- low level of red blood cells in blood (anaemia) which can make you feel lethargic and very tired.

These changes can only be found when your doctor does tests from time to time to check your progress.

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 FORTEO contains

Active ingredient (main ingredient)	teriparatide
Other ingredients (inactive ingredients)	glacial acetic acid sodium acetate

Active ingredient (main ingredient)	teriparatide
	mannitol metacresol water for injections hydrochloric acid sodium hydroxide

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

What FORTEO looks like

FORTEO is a clear and colourless liquid. It is supplied in a 2.4mL cartridge contained in a prefilled delivery device (pen) that delivers 20 mcg per dose and contains dosing for 28 treatment days. (AUST R 80333).

FORTEO is available in packs of one.

Who distributes FORTEO

Eli Lilly Australia Pty Ltd
Level 9, 60 Margaret Street
Sydney NSW 2000

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