

FORTEO®

Teriparatide (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FORTEO. It does not contain all the available information and does not take the place of talking to your doctor or health care professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you using FORTEO against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or health care professional.

Keep this leaflet with the medicine.

You may need to read it again.

What is the most important information I should know about FORTEO?

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.

What FORTEO is used for

FORTEO is used to treat osteoporosis in women after menopause and in men.

Osteoporosis is a disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break. This disease is especially common in women after the menopause. 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.

This medicine is a recombinant parathyroid hormone.

It works by activating cells in the bone to form new bone. Using this medicine each day will protect your bones by making them stronger and your risk of fracture will be reduced.

Your doctor may have prescribed it for another reason.

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

This medicine is not expected to affect your ability to drive a car or use machinery. Some patients may feel dizzy after injecting FORTEO. If you feel dizzy you should not drive or use machines until you feel better.

Before you use FORTEO

Your health care professional should teach you how to use the FORTEO pen. You should also read the user manual for information on how to use the pen before beginning therapy. Read the user manual and package leaflet each time you get a new pen, in case something has changed.

When you must not use it

Do not use FORTEO if:

- **you have previously received FORTEO therapy for a total of 24 months. 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 are pregnant or breast-feeding.
- you have high calcium levels in the blood (hypercalcaemia).
- you have severe kidney disease.
- you have ever had metabolic bone disease (including Paget's disease of the bone or hyperparathyroidism) other than primary osteoporosis or

glucocorticoid-induced osteoporosis.

- you have ever had bone cancer or other cancers that have spread (metastasised) to your bones.
- you have unexplained high levels of a liver enzyme called alkaline phosphatase (ALP) in the blood.
- you have ever had external beam or implant radiation therapy to the skeleton.
- you have an open epiphysis (rounded portion of the bone).
- you have an allergy to any medicine containing teriparatide or any of the ingredients listed at the end of this leaflet.

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.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to use it

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.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- high calcium levels in the blood (pre-existing hypercalcaemia). Signs and symptoms of high calcium in the blood may include continuing nausea, vomiting, constipation, low energy, or

muscle weakness. FORTEO may cause an increase in the amount of calcium in your blood or urine.

- bone disorders other than osteoporosis (including hyperparathyroidism)
- high levels of alkaline phosphatase
- have had radiation therapy
- calculi or stones (mineral deposits) in the urinary tract
- low blood pressure
- kidney disease.

This medicine should not be used in children or in young adults if their bones have not finished growing (open epiphyses).

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

This medicine should not be used if you are pregnant or breast-feeding.

Before you start using FORTEO, tell your doctor about any of the above conditions.

Taking other medicines

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

Some medicines and FORTEO may interfere with each other, e.g.

- 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 (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 your medicine. 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 this medicine.

How to use FORTEO

Carefully follow all directions given to you by your doctor or health care 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 health care professional for help.

How much to use

The usual dose is 20 mcg given once a day.

How to use it

FORTEO is given by injection under the skin (subcutaneous) into the thigh or abdomen.

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.

When to use it

You can take FORTEO at any time of day.

To help you remember, use your medicine at about the same time each day.

Using it at the same time each day will have the best effect.

How long to use it

The safety and efficacy of FORTEO have not been evaluated beyond 2 years (median treatment is 19 months in postmenopausal women).

Use of the drug for more than 24 months lifetime duration is not recommended.

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

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 it

Have it as soon as possible on that day. Do not have more than one injection on the same day. Then go back to using your medicine as you would normally.

Do not have double injections to make up for the injection that 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 health care professional.

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

If you have too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have had too much FORTEO. Do this even if there are no signs of discomfort or poisoning. 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 and headache may also occur.

While you are using FORTEO

Things you must do

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

Tell any other doctors, dentists and health care professionals who treat you that you are using this medicine.

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 become pregnant while using this medicine, tell your doctor immediately.

If you are a woman of childbearing potential, you should use effective methods of contraception during treatment with FORTEO.

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.

Things you must not do

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.

Do not stop using your medicine without checking with your doctor.

Side effects

Tell your doctor or health care professional as soon as possible if you do not feel well while you are using FORTEO.

This medicine helps most people with osteoporosis, but it may have unwanted side effects in a few people. Most of the side effects are mild.

Ask your doctor or health care professional to answer any questions you may have.

Tell your doctor or health care professional if you notice any of the following and they worry you:

- 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
- sluggishness, fatigue, mental fog, and reduced urination

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.

The above list includes the more common side effects of your medicine.

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

Other side effects not listed above may also occur in some people. Some of these side effects (for example, a high amount of uric acid or calcium levels, or a low level of red blood cells in the blood (anaemia)) can only be found when your doctor does tests from time to time to check your progress.

Allergic reactions may occur in some people. This may be seen as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips or tongue, rash, itching or hives on the skin.

After using FORTEO

Storage

Keep your FORTEO pen in the refrigerator where the temperature stays between 2°C to 8°C. Do not allow FORTEO to freeze. Do not use FORTEO if it has been frozen.

Keep it where children cannot reach it.

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.

You should use a new needle for each injection. 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.

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.

FORTEO is a clear and colourless liquid. Do not use if solid particles appear or if the solution is cloudy or coloured.

Disposal

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.

If the expiry date on this medicine has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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.

FORTEO is available in packs of one.

Ingredients

FORTEO contains 250 mcg/mL of teriparatide as the active ingredient.

It also contains:

- glacial acetic acid
- sodium acetate
- mannitol
- metacresol
- water for injections
- hydrochloric acid may have been added to adjust product pH
- sodium hydroxide may have been added to adjust product pH.

Supplier

FORTEO is a product of:

Eli Lilly Australia Pty Limited

112 Wharf Road

WEST RYDE NSW 2114

®= Registered Trademark

Australian Registration Number:

AUST R 80333