

PATIENT INFORMATION ON TERIPARATIDE

(Brand name: Forteo®)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **the possible side effects**
- **other precautions you should take while you are taking teriparatide.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking teriparatide you should see your rheumatologist or other specialist regularly to make sure the treatment is working and to minimise any possible side effects.
- If you are worried about any side effects you should contact your specialist as soon as possible.
- Teriparatide should *not* be taken with some other osteoporosis medicines such as bisphosphonates e.g. alendronate (Fosamax, Alendro, Fosamax Plus), risedronate (Actonel, Actonel Combi, Actonel Combi D) and zoledronate (Aclasta), or denosumab (Prolia), strontium (Protos) or raloxifene (Evista). These should be stopped before you start teriparatide.

For more information about OSTEOPOROSIS see the Osteoporosis Australia website www.osteoporosis.org.au/ or phone Osteoporosis Australia on 1800 242 141.

What is teriparatide?

Teriparatide (brand name: Forteo®) is a medicine used to treat severe osteoporosis. Osteoporosis is a common disease that causes bones to become fragile and brittle so that they break (fracture) more easily even as a result of normal activity (as distinct from a fall).

Fractures are painful and restrict a person's ability to carry out their normal daily tasks. Teriparatide reduces the risk of a broken bone or fracture.

How does it work?

Bone is constantly changing with older bone being broken down and new bone being formed to take its place. This usually happens in a balanced way. If the cycle becomes unbalanced bone breaks down faster than it is replaced. This leads to osteoporosis.

Teriparatide is a man-made form of a substance called parathyroid hormone, which is found naturally in the body and has an important role in maintaining healthy bones. Teriparatide increases bone formation thereby increasing bone strength and reducing the risk of fracture.

What benefit can you expect from your treatment?

Since osteoporosis is usually not painful (until a fracture occurs) you will not 'feel' any immediate benefit from your treatment with teriparatide.

The treatment controls osteoporosis but does not cure it. It is therefore important to continue to use teriparatide even if you feel well.

Do not stop using teriparatide until advised by your doctor.

You may be asked to have tests to check the effect of treatment on your bones. For example a bone mineral density test is usually done one or two years after first starting teriparatide. This is a type of X-ray that involves a very small amount of radiation.

Tests of urine or blood are also sometimes used to measure the effects of treatment on bone formation and breakdown.

How is teriparatide used?

To make sure it is effective it is very important that you follow the instructions for using teriparatide carefully, including the instructions for storage and disposal. Ask your doctor or pharmacist to explain anything you do not understand.

Teriparatide is given as an injection under the skin (subcutaneously). It is injected in the thigh or abdomen once a day. It comes in a pen-shaped device to make the daily injection easier. The teriparatide pen contains enough medicine for 28 doses.

It is important to use a new needle for each injection.

What is the dosage and when should it be given?

The teriparatide daily dose is 20 micrograms.

Use it at around the same time every day to help you remember. The best time to take it is at night before going to bed.

If a dose is missed use it as soon as possible that day. However, if the day has already passed, skip the missed dose and continue your regular dosing schedule. **Never** inject more than one dose per day. Do not use more or less teriparatide or use it more often than prescribed by your doctor.

Can other medicines be taken with teriparatide?

It is safe to take most other medicines when you are taking teriparatide. However, teriparatide should **not** be taken with some other osteoporosis medicines (see *Precautions*).

Your doctor will usually recommend that you take calcium and vitamin D as additional treatment for osteoporosis. Do not stop taking these medicines unless advised by your doctor.

How long is the treatment continued?

For osteoporosis, treatment with teriparatide is usually given continuously for up to 18 months and no longer. After that further treatment with an alternative medicine for osteoporosis is recommended.

Are there any side effects?

Most people who take teriparatide do not experience side effects. Tell your doctor if you are concerned about possible side effects.

Most common possible side effects

The most common side effects include:

- *nausea, vomiting or constipation*
- *pain in joints or bones*
- *headache*
- *dizziness or lightheadedness*: this can happen if you get up too quickly from a lying position. It is more common at the start of treatment. By getting out of bed slowly and resting your feet on the floor for a few minutes before standing up you can reduce the risk. It is a good idea to have a chair nearby when you give yourself the injection so that you can sit down if you feel dizzy.
- *discomfort around the injection site* can occur in up to 30% of people and may include pain, swelling, bruising, itching or a few drops of blood.

Less common or rare possible side effects

Less common side effects include:

- *muscle weakness*
- *heartburn*
- *leg cramps or back spasms*
- *depression*
- *chest pain or difficulty breathing*
- *lack of energy.*

There are a number of other uncommon side effects and precautions. These are described in the leaflet that comes with the medicine. Read this information and discuss any concerns with your doctor.

Warning of very rare side effect

Teriparatide has been found to cause an increased risk of bone cancer (sarcoma) when used in animals in high doses continuously from birth. It is for this reason that the maximum lifetime duration of teriparatide is only 18 months.

Because of these restrictions your prescribing doctor will ask you to sign a form about treatment with this medicine.

What precautions are necessary?

Blood tests

- Monitoring blood tests are not usually required for people taking teriparatide, although in certain situations these may be needed.

Other medical conditions

- Teriparatide should **not** be taken if you have:
 - severe kidney disease or kidney failure
 - Paget's disease or blood tests suggestive of Paget's disease
 - bone diseases other than osteoporosis
 - high parathyroid hormone levels
 - a history of bone cancer or
 - any previous radiotherapy.

Use with other medicines

- You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when you see other health professionals.
- Teriparatide should **not** be taken with some other osteoporosis medicines such as bisphosphonates e.g. alendronate (Fosamax,

Alendro, Fosamax Plus), risedronate (Actonel, Actonel Combi, Actonel Combi D) and zoledronate (Aclasta), or denosumab (Prolia), strontium (Protos) or raloxifene (Evista). These should be stopped before you start teriparatide.

- Bisphosphonates may be started or recommenced following teriparatide treatment.
- The risk of side effects from the low doses of aspirin used to prevent heart attack and strokes is not increased when taken with teriparatide.

How to store and dispose of teriparatide

- Keep the medicine in the pen it came in with the cap on and without a needle attached, tightly closed, and out of reach of children.
- Do not transfer the medicine to a syringe.
- Store it in the refrigerator but do not freeze it.
- Protect it from light.
- Throw away any medicine that is outdated or no longer needed.
- Throw away the pen after 28 days of use even if it is not empty.
- Dispose of used needles in a puncture-resistant container (sharps box). Talk to your doctor or pharmacist about how to dispose of the sharps box.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

If you are taking teriparatide you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.