

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



Patient Information Leaflet

SCHEDULING STATUS: **S4**

TERATYDE, 250 µg/ml, Solution for injection
(Teriparatide)

Preservative: metacresol 0,3 % *m/v*.

Read all of this leaflet carefully before you start using TERATYDE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TERATYDE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TERATYDE is and what it is used for
2. What you need to know before you use TERATYDE
3. How to use TERATYDE
4. Possible side effects
5. How to store TERATYDE
6. Contents of the pack and other information

1. What TERATYDE is and what it is used for

TERATYDE contains the active substance teriparatide. It is used to make the bones stronger, and to reduce the risk of fractures by stimulating bone formation.

TERATYDE is used to treat osteoporosis in adults. Osteoporosis is a disease that causes your bones to become weak and thus making them fragile. This disease is especially common in women after menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

2. What you need to know before you take TERATYDE

Do not use TERATYDE:

- if you are hypersensitive (allergic) to teriparatide or to any of the other ingredients of this medicine (listed in section 6);
- if you suffer from high calcium levels;
- if you have high levels of an enzyme, alkaline phosphatase;
- if you have certain bone diseases;
- if you have ever been diagnosed with bone cancer or other cancers that have spread to your bones;
- if you have had radiation therapy involving your bones;
- if you are pregnant or breast-feeding;
- if you suffer from serious kidney problems.

Warnings and precautions

Take special care with TERATYDE:

- if you have continuous nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs of too much calcium in your blood;

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



- if you are a woman of childbearing potential. You should make use of an effective method of contraception;
- if you are premenopausal women;
- if you suffer from kidney stones or have a history of kidney stones;
- if you suffer from any kidney problems.
- If you experience a drop in blood pressure when standing up, it is advised to receive TERATYDE in a laying down position for the first several doses.

Monitor calcium levels in blood regularly during treatment with TERATYDE.

Children and adolescents

TERATYDE should not be given to children below 18 years of age.

Other medicines and TERATYDE

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines)

- Tell your healthcare provider if you are taking digoxin/digitalis, a medicine used to treat heart disease.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy:

Do not use TERATYDE if you are pregnant. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of TERATYDE.

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



Breastfeeding:

Do not use TERATYDE while you are breastfeeding.

Driving and using machines

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

3. How to take TERATYDE

Do not share medicines prescribed for you with any other person.

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

The recommended dose is 20 micrograms given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen. To help you remember to use your medicine, inject it at about the same time each day.

Inject TERATYDE each day for as long as your doctor prescribes it for you. The total duration of treatment with TERATYDE should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

You should use TERATYDE injection shortly after you take the pen out of the refrigerator. Put the pen back into the refrigerator immediately after you have used it. Use a new injection needle for each injection and dispose of it after each use. Never store your pen with the needle attached. Never share your TERATYDE pen with others even if the needle is changed.

Your doctor may advise you to use TERATYDE with calcium and vitamin D. Your doctor will tell you how much you should use each day.

TERATYDE can be injected at mealtimes.

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



If you use more TERATYDE than you should

If by mistake, you have used more TERATYDE than you should, consult your doctor or pharmacist. You may experience effects such as nausea, vomiting, dizziness, and headache.

If you forget to use TERATYDE

If you forget to use TERATYDE at your usual time, use it as soon as possible on that day. Do not use a double dose to make up for forgotten individual doses.

If you stop using TERATYDE

If you are considering stopping TERATYDE treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with TERATYDE.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

TERATYDE can have side effects.

Not all side effects reported for TERATYDE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TERATYDE, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking TERATYDE and tell your doctor immediately or go to the casualty department at your nearest hospital:

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



- Anaphylaxis (sudden life threatening allergic reaction. Symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing);
- Possible allergic reactions soon after injection: swelling of mouth and face, hands, ankles or feet, hives, chest pain, peripheral oedema (swelling due to retained fluid).

These are very serious side effects. If you have them, you may have had a serious reaction to TERATYDE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fast or irregular heartbeats;
- Chest pain;
- Cardiac murmur (heart murmur. Blowing, whooshing, or rasping sound heard during a heartbeat);
- Dyspnoea (difficulty breathing or shortness of breath);
- Emphysema (serious lung disease that makes breathing difficult. Symptoms include shortness of breath with cough);
- Kidney failure (symptoms may include decreased urinary output, swelling due to fluid retention, nausea, fatigue and shortness of breath).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Anaemia (decreased number of red blood cells. Symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale);
- Increased cholesterol levels in blood;

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



- Depression;
- Headache;
- Dizziness, fainting;
- Pain radiating along the sciatic nerve, which runs down one or both legs from the lower back;
- Palpitations (Rapid irregular action of the heart)
- Low blood pressure. Symptoms may include feeling dizzy, confusion, cold skin, rapid and shallow breathing;
- Nausea, vomiting;
- Hernia of the tube that carries food to your stomach;
- Heartburn (painful or burning sensation just below the breastbone);
- Increased sweating;
- Pain in limb;
- Muscle cramps;
- Tiredness, unusual weakness, injection site events including pain, swelling, redness, localised bruising, itching and minor bleeding.

Less frequent side effects:

- High calcium levels in blood. Symptoms may include loss of appetite, nausea, vomiting, constipation, stomach pain;
- High uric acid levels in blood. Symptoms may include severe pain in your joints, joint stiffness, difficulty moving affected joints, redness and swelling of joints;
- Piles;
- Muscle pain, joint pain, back pain;
- Loss of bladder control;
- Kidney stones

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



- Weight increased,
- Increased level of an enzyme, alkaline phosphatase in blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurses. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TERATYDE.

Suspected adverse reactions can also be reported directly to the Holder of Certificate of Registration (HCR) via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000

5. How to store TERATYDE

Store all medicines out of reach of children.

Store in a refrigerator between 2 °C and 8 °C.

Do not freeze. Do not use **TERATYDE** if it has been frozen.

The **TERATYDE** prefilled delivery device should be discarded 28 days after the first injection from the device, even if there is solution left in the pen.

6. Contents of the pack and other information

What TERATYDE contains

The active substance is ertapenem.

Each vial contains ertapenem 1 g

The other ingredients are: Sodium bicarbonate, sodium hydroxide, water for injection, nitrogen

What TERATYDE looks like and contents of the pack

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd

Product proprietary name: Teratyde

Dosage form and strength: Solution for injection / Teriparatide 250 µg per ml



TERATYDE

A clear colourless solution free from visible particulate matter, filled in a plunger stoppered glass cartridge.

TERATYDE is available in pack sizes of 1's. Each pen contains 28 doses of 20 micrograms (per 80 microlitres).

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

Telephone: +27(0) 12 643 2000

This leaflet was last revised in

22 July 2025

Registration number

58/21.4/0003