

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Teriparatide Teva

Solution for injection in a pre-filled pen

Composition:

250 mcg/ml teriparatide (as acetate)

Each injected dose (80 microliter) contains:

20 mcg teriparatide (as acetate)

For information about inactive ingredients and allergens: see section 2 – 'Important information about some of this medicine's ingredients' and section 6 – 'Additional Information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. Also read the User Manual of the Teriparatide Teva pen.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

Please note that, every time you get this medicine at the pharmacy, it is important that you check that you have been given the same medicine that your specialist has prescribed you. If the medicine you are given looks different from what you usually get, or if the instructions for use have changed, please consult your pharmacist immediately to make sure you received the correct medicine. Only your specialist can switch your medicine or change the dosage of medicine that contains teriparatide (the active ingredient in this medicine). Please check that the medicine that your specialist prescribed you has the same brand name as the medicine you got from the pharmacist.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as having a history of osteoporotic fracture or multiple risk factors for fracture) or who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Teriparatide Teva reduces the risk of vertebral and non-vertebral fractures.
- to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, or who have failed or are intolerant to other available osteoporosis therapy.
- For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.

Therapeutic group:

calcium homeostasis, parathyroid hormones and analogues.

2. BEFORE USING THIS MEDICINE:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (teriparatide) or to any of the other ingredients that this medicine contains (see section 6 'Additional Information'). Symptoms of a serious allergic reaction to teriparatide may include swelling of the face, lips, tongue or throat that may cause difficulty in breathing or swallowing. Call your doctor right away or get emergency medical help if you get these symptoms.

Special warnings regarding use of this medicine

Teriparatide Teva may cause bone cancer: During drug testing, teriparatide caused some rats to develop a bone cancer called osteosarcoma.

Studies in humans have not shown that teriparatide increases your chance of getting osteosarcoma. There is little information about the chance of getting osteosarcoma in patients using teriparatide beyond 2 years.

Before using Teriparatide Teva, tell your doctor if:

- you have a certain bone disease called Paget's disease or some other bone disease
- you have bone cancer or have a history of bone cancer
- you are a young person and are still growing
- you have had radiation therapy
- you have a condition that runs in your family that can increase your chance of getting bone cancer
- you have or have had too much calcium in your blood (hypercalcemia)
- you have or have had a skin condition with painful sores or bruises caused by too much calcium
- you have or have had kidney stones
- you take medicines that contain digoxin
- you are pregnant or plan to become pregnant. It is not known if teriparatide will harm your unborn baby.
- you are breastfeeding or plan to breastfeed. It is not known if teriparatide passes into breastmilk. You should not breastfeed while taking Teriparatide Teva.

Children and adolescents

It is not known if this medicine is effective and safe in children.

This medicine is not intended for children or adolescents whose bones are still growing.

Tests and follow-up

During treatment with this medicine, your doctor may check the calcium levels in your urine.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Especially, tell your doctor or pharmacist if you are taking or plan to take:

- Medicines that contain digoxin – reported cases show that hypercalcemia may cause digoxin toxicity. Teriparatide Teva may temporarily increase calcium levels. Therefore, the signs and symptoms of digoxin toxicity should be considered when patients taking digoxin are also taking Teriparatide Teva.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

Using this medicine and food

You can inject at any time of the day, regardless of meal times or drinking.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant, think you are pregnant, or plan to become pregnant, consult your doctor before using this medicine. It is not known if teriparatide will harm your unborn baby.

Breastfeeding

If you are breastfeeding or plan to breastfeed, contact your doctor before using this medicine. It is not known if teriparatide passes into breastmilk.

Do not breastfeed while taking Teriparatide Teva.

Driving and using machines

Use of this medicine may cause dizziness (see section 4 – 'Side effects'). If you experience this, avoid driving or operating machines.

Important information about some of this medicine's ingredients

Teriparatide Teva contains less than 23 mg sodium per dose and is therefore considered sodium free.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

Read the detailed Instructions for Use (User Manual) included with your Teriparatide Teva pen.

- Use Teriparatide Teva exactly as your doctor tells you to. Your doctor will tell you how much Teriparatide Teva to use and when to use it.
- Before you try to inject Teriparatide Teva yourself, your doctor will show you how to use the Teriparatide Teva pen to inject your dose.
- The recommended dose is usually one injection of Teriparatide Teva per day, in your thigh or abdomen (lower stomach area). Do not inject into a vein or a muscle. Consult your doctor about how to rotate injection sites.
- The Teriparatide Teva pen has enough medicine for 28 days. Teriparatide Teva is set to give a 20-microgram dose of medicine each day. Do not inject all the medicine in Teriparatide Teva at any one time.
- Do not transfer the medicine from the Teriparatide Teva pen to a syringe. This can result in taking the wrong dose of Teriparatide Teva. If you do not have needles to use with your Teriparatide Teva pen, talk with your doctor.
- Teriparatide Teva should look clear and colorless. Do not use Teriparatide Teva if it has solid particles in it, or if it is cloudy or colored.
- Inject Teriparatide Teva right after you take the pen out of the refrigerator.
- After each use, carefully remove the needle, recap the pen, and put it back in the refrigerator right away.
- When you inject the first few doses of Teriparatide Teva, make sure you are in a place where you can sit or lie down right away, in case you feel dizzy or have an abnormal heartbeat after the injection.

- Do not take more than one injection in one day.
- Do not share your Teriparatide Teva pen with other people.
- Do not use Teriparatide Teva for more than 2 years over your lifetime, unless your doctor finds that you need longer treatment (up to 3 years) because you have a high chance of breaking your bones.
- If your doctor recommends calcium and vitamin D supplements, you can take them with Teriparatide Teva.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose, or if a child has swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. If you take too much Teriparatide Teva, you may have nausea, weakness/lethargy, and low blood pressure. Additional signs, symptoms, and complications of Teriparatide Teva overdose may include delayed hypercalcemic effect, vomiting, dizziness, and headache.

Follow the treatment as recommended by your doctor.

You should complete the course of treatment recommended by your doctor. Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Teriparatide Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Teriparatide Teva can cause serious side effects including:

- **Bone cancer (osteosarcoma):** Tell your doctor right away if you have pain in your bones, pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that are tender to touch.
- **Increased calcium in your blood.** Tell your doctor if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- **Worsening of your kidney stones.** If you have or have had kidney stones, your doctor may check the calcium levels in your urine while you use Teriparatide Teva to see if the condition is getting worse.
- **Decrease in blood pressure when you change positions.** Some people may feel dizzy or get a fast heartbeat right after the first few doses of Teriparatide Teva. This usually happens within 4 hours of taking Teriparatide Teva and goes away within a few hours. For the first few doses, take Teriparatide Teva in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, contact your doctor before you continue using Teriparatide Teva.

The most common side effects of Teriparatide Teva include:

- pain
- nausea
- joint aches

Side effects observed in studies of postmenopausal women with osteoporosis and men with primary or hypogonadal osteoporosis:

- **Body as a whole:** pain, headache, weakness, neck pain.
- **Heart and blood vessels:** hypertension, angina pectoris, temporary loss of consciousness (fainting).
- **Digestive system:** nausea, constipation, diarrhea, dyspepsia, vomiting, gastrointestinal disorders, tooth problems.
- **Musculoskeletal system:** joint pain, leg cramps.
- **Nervous system:** dizziness, depression, insomnia, vertigo.
- **Respiratory system:** runny nose, cough increased, pharyngitis, shortness of breath, pneumonia.
- **Skin:** rash, sweating.

Side effects observed in studies of women and men with corticosteroid therapy-related osteoporosis:

- nausea
- stomach inflammation (gastritis)
- pneumonia
- shortness of breath
- insomnia
- anxiety
- Herpes zoster

Side effects of unknown frequency observed after the medicine was marketed – It is not possible to reliably estimate their frequency or establish a causal relationship to medicine exposure.

- Cases of bone tumor and osteosarcoma have been reported rarely in the post-marketing period.
- Hypercalcemia: high level of calcium in the blood.

Side effects reported since market introduction that were temporally related to teriparatide therapy include:

- Allergic reactions: anaphylactic reactions, hypersensitivity to the medicine, angioedema, urticaria.
- Laboratory results: an increase in the level of uric acid in the blood.
- Respiratory system: acute shortness of breath, chest pain.
- Musculoskeletal system: spasms in the muscles of the leg or back.
- Other: injection site reactions including injection site pain, swelling, bruising; facial edema.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store in a refrigerator (2°C–8°C).

Do not freeze. Do not use the medicine if it has been frozen.

Teriparatide Teva may be used within 28 days of the first injection, provided the pen was stored in the refrigerator (2°C–8°C).

Discard the pen after 28 days even if it still has medicine in it. See the User Manual.

Teriparatide Teva contains a clear and colorless solution. Do not use Teriparatide Teva if it has solid particles in it, or if the solution is cloudy or colored.

Unopened pen:

The unopened pen may be removed from the refrigerator and stored at a temperature up to 25°C for a period of up to 5 days, after which you should return it to the refrigerator (2°C – 8°C). You may only do this once. Discard the unopened pen if stored above 8°C for more than 5 days.

Do not dispose of any medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Mannitol, metacresol, glacial acetic acid, sodium acetate trihydrate, hydrochloric acid, sodium hydroxide, water for injections.

What the medicine looks like and contents of the package:

A pre-filled pen with a clear, colorless solution.

Each 2.4 ml pre-filled pen contains 600 mcg teriparatide and is sufficient for 28 days of treatment.

Packages contain 1 or 3 pre-filled pens.

Not all package sizes may be marketed.

Name and address of the license holder and manufacturer:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel-Aviv 6944020.

Revised in July 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 163.24.35333

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