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

This medicine is dispensed with a doctor's prescription only

Teriparatide Teva

Solution for subcutaneous injection in a pre-filled pen

Name and quantity of active ingredient:
Each injected dose (80 microliters) contains:
Teriparatide (as acetate) 20 microgram

For additional information about inactive ingredients, 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. Also read the user manual of the Teriparatide Teva pen. If you have any further questions, consult your doctor or pharmacist.

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 a 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 received from the pharmacist.

1. What is this medicine intended for?

- For treatment of postmenopausal women and men who are suffering from osteoporosis and are at high risk of developing fractures.
- For treatment of osteoporosis associated with corticosteroid therapy in men and women at increased risk for fractures.
- Teriparatide increases bone mineral density (BMD), strengthens the bone, and reduces the risk of fractures.

Therapeutic group:
Parathyroid hormones

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (see section 6). Reactions include angioedema and anaphylactic reaction.

Special warnings about using this medicine:
- There have been rare reports of bone cancer (osteosarcoma) among patients who had been taking Teriparatide Teva. In people, osteosarcoma is a serious but rare cancer. It is not known whether the risk of developing this condition is higher among patients who take Teriparatide Teva.
- The duration of treatment is limited to two years over your lifetime.

Before using Teriparatide Teva, tell your doctor if:
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine.
- You suffer, or have suffered in the past, from impaired function of the kidneys/urinary tract, from stones in your kidneys or urinary tract or from a high level of calcium in your urine.
- You suffer from Paget's disease or another bone disease.
- You have bone cancer.
- You have trouble injecting the medicine yourself and do not have someone who can help you with the injection.
- You are a child or young adult and are still growing.
- You have had radiation therapy.
- You suffer or have suffered in the past from high levels of calcium in the blood or from diseases that cause high levels of calcium in the blood such as an overactive thyroid (hyperparathyroidism).
- You have any other medical condition.
- You are pregnant or planning to get pregnant.
- You are breastfeeding or planning to breastfeed.

Children and adolescents
This medicine is not intended for children or young adults who are still growing.

Tests and follow-up
During the course of treatment with this medicine, your doctor may refer you for blood and urine tests to check your response to Teriparatide Teva. In addition, your doctor may refer you for follow-up tests of bone mineral density.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly, tell your doctor or pharmacist if you are taking or planning to take:
- Digoxin: Teriparatide Teva may increase calcium levels. Therefore, extreme care must be taken when using Teriparatide Teva in patients taking digoxin.

Using this medicine and food:
You may inject at any time of the day, regardless of meal or drinking times.

Pregnancy and breastfeeding
Pregnancy
There are no available data on teriparatide use in pregnant women to evaluate for drug-associated risk of major birth defects, miscarriages, or unwanted outcomes for both mother and fetus. If you are pregnant, consider discontinuing Teriparatide Teva treatment.

Breastfeeding
It is unknown whether teriparatide is excreted in breast milk, or whether it affects breast milk production or the breastfed infant. Do not breastfeed during Teriparatide Teva treatment.

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. The standard dosage is usually one subcutaneous injection daily, in the thigh or lower abdomen (lower stomach area).
Consult your doctor about how to rotate between injection sites.

Do not exceed the recommended dose.
- Duration of treatment is limited to two years over your lifetime.
- This medicine should be used at specific times as determined by your doctor.
- Teriparatide Teva is intended for subcutaneous injection. Before using Teriparatide Teva, carefully read the user manual enclosed in the package. Use the pre-filled pen according to the detailed instructions in the user manual.
- The Teriparatide Teva injection fluid should look clear and colorless. Do not use your Teriparatide Teva if it has particles in it, or if it is cloudy or colored.
- You can inject Teriparatide Teva at any time of the day. To help you remember, it is recommended that you inject the medicine at the same time every day.
- Your doctor or nurse should teach you how to use Teriparatide Teva before you try to inject yourself with Teriparatide Teva, so that you will be able to inject the medicine correctly.
- At the beginning of treatment, administer the medicine where you can sit or lie down in case you get orthostatic hypotension when changing position from lying down to standing up, which is experienced as dizziness, weakness, feeling faint, and rapid heartbeat. .
- Important to remember: You must inject the dose shortly after you take the pre-filled pen out of the refrigerator in the manner explained in the user manual.
- After each use, carefully remove the needle and recap the pen and put it back in the refrigerator right away.
- Do not transfer the contents of the pen into another syringe. This can result in taking a wrong dose of Teriparatide Teva. Contact your doctor if you do not have needles to use with your injector pen.
- Use the pen within 28 days of the first use.
- Discard the pen at the end of the 28-day period, even if it still contains solution.
- Teriparatide Teva contains enough medicine for 28 days. Teriparatide Teva is intended to provide a 20-microgram dose of medicine each day. Do not inject all the medicine in your Teriparatide Teva at once.
- Follow your doctor's instructions about other ways you can treat your osteoporosis, such as exercise, diet, and reducing or stopping tobacco and alcohol use. If your doctor recommends calcium and vitamin D supplements, you can take them at the same time as you take Teriparatide Teva.

If you have accidentally injected a higher dose, or if a child has swallowed some medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the medicine package with you. Side effects have been reported, including nausea, vomiting, weakness, dizziness, headache, orthostatic hypotension when changing position from lying down to standing up. There may also be an increase in the level of calcium in the blood (hypercalcemia).

If you forget, or if you can't take the medicine on time, take it as soon as you can that day. Do not inject Teriparatide Teva more than once a day. Adhere to the treatment as recommended by the doctor.

You should complete the full course of treatment as recommended by your doctor. Even if your health improves, 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 a 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:

Like with all medicines, 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:
- Osteosarcoma: Cases of osteosarcoma (bone cancer) and bone tumor have been rarely reported.
- Orthostatic hypotension when changing position from lying down to standing up. Some users feel dizzy, get a fast heartbeat or feel faint right after taking the first few doses. This usually happens within 4 hours of taking Teriparatide Teva and goes away within a few hours. For the first few doses, use Teriparatide Teva in a place where you can sit or lie down right away if you feel these symptoms. If your symptoms get worse or do not go away, stop taking Teriparatide Teva and call your doctor.
- Increased calcium in your blood.

Tell your doctor if you experience side effects that might indicate high blood calcium levels, such as: nausea, vomiting, constipation, low energy or muscle weakness.

Common side effects:
- Nausea
- Pain
- Joint pain

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

Side effects observed in studies among patients with osteoporosis associated with corticosteroid therapy:
- Nausea
- Stomach inflammation (gastritis)
- Pneumonia
- Shortness of breath
- Insomnia
- Anxiety
- Herpes zoster

Side effects with unknown frequency were observed after the drug was marketed - it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
- Osteosarcoma: Cases of bone tumor and osteosarcoma have been reported rarely in the post-marketing period.
- Hypercalcemia: high level of calcium in the blood.

Temporary side effects reported since market introduction, but not necessarily causally related to teriparatide therapy, include:
- Allergic reactions: anaphylactic reactions, drug hypersensitivity, angioedema, urticaria
- Laboratory results: an increase in the level of uric acid in the blood
- Respiratory system: severe dyspnea, chest pain
- Musculoskeletal: muscle cramps in the legs or back
- Other: **Side effects** at the injection site include: pain at the injection site, 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 of Drug Treatment' 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 this medicine?

- Avoid poisoning! To avoid poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:
- Keep refrigerated (2°C-8°C).
- Do not freeze. Do not use medicine that has been frozen.
- Use within 28 days of the first injection.
- Discard the Teriparatide Teva pen after 28 days even if it still contains some solution.
- Do not use the pen if the solution appears cloudy or colored, or has solid particles in it.

Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away 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 pack:
A pre-filled pen containing a clear and colorless solution.
The pen is intended for multiple administrations and must be discarded when used up.

Each 2.4 ml syringe contains 600 mcg teriparatide, sufficient for 28 days of treatment.
Each pack contains 1 or 3 pre-filled pens. Not all pack sizes may be marketed.

Registration holder and manufacturer's name and address:
Teva Israel Ltd.,
124 Devora HeNevia, Tel-Aviv 6944020.

This leaflet was revised in July 2022 according to Ministry of Health guidelines.

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