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

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. 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 to 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 received from the pharmacist.

This medicine is not intended for children or young people who are still in their growing stage.
Duration of treatment is limited to two years.

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 Teva** increases bone mineral density (BMD), strengthens the bone and reduces the risk for 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. Signs of allergic reaction include: rash, difficulties swallowing or breathing, swelling of the lips, face, throat or tongue (angioedema) (see section 6).
- You are pregnant or planning to get pregnant
- You are breastfeeding
- You are unable to inject the medicine yourself and there is nobody nearby who can help you with administration of the injection
- You suffer from Paget's disease or if there is an unexplained high level of alkaline phosphatase in your blood that may indicate Paget's disease
- You suffer, or have suffered in the past from hypercalcemia
- You have been diagnosed with a metabolic bone disease or bone tumors or if you have had radiation therapy for the bones
- You suffer from severe renal impairment
- You are a child or a young person who is still in the growing stage
- You suffer from hyperparathyroidism

Special warnings about using this medicine:

- In the event that your regular diet is not sufficient, your doctor may recommend that you take calcium and vitamin D. You must consult the doctor regarding the standard dose for these supplements.
- Women of childbearing age should use effective contraceptives and consult their doctor.
- There have been rare reports of bone cancer (osteosarcoma) among patients who had been taking **Teriparatide Teva**. Whether the risk of developing this condition is higher among patients who take **Teriparatide Teva** is unknown.

Before using Teriparatide Teva, tell your doctor if:

- You suffer, or have suffered in the past, from impaired function of the kidneys/urinary tract, from stones in the urinary tract or from hypercalciuria, so that your doctor can follow up on your urine calcium levels.
- You suffer from low blood pressure during transition from a lying to standing position (orthostatic hypotension).
- You suffer from any bone disease.
- You are sensitive to any food or medicine.

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:

Digitalis preparations (digoxin) for your heart – calcium affects the mechanism of action of digoxin, and **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 times.

Pregnancy and breastfeeding:

- Do not use this medicine if you are pregnant or breastfeeding (see “Do not use this medicine if”). If you get pregnant during treatment, you must discontinue the use of **Teriparatide Teva** immediately.
- If you are breastfeeding and your doctor decided that you should use this medicine, you should stop breastfeeding. It is unknown whether **Teriparatide Teva** is excreted in breast milk.

Driving and using machines:
Use of this medicine may cause dizziness (see "Side effects" section). In case 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 as 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.
- **Do not exceed the recommended dose**.
- Duration of treatment is limited to two years.
- This medicine should be used at specific time intervals 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. Please use the pre-filled pen according to the instructions detailed in the manual.
- For your convenience and to help you remember, it is recommended that you inject the medicine at the same time each day.
- At the beginning of treatment, administer the medicine where you can sit or lie down in case you feel dizzy or experience irregular heartbeat caused by hypotension during transition from a lying to standing position.
- **Use a new needle for each injection. Do not leave a used needle attached to the pen in order to prevent leakage of the solution from the pen or penetration of air into the cartridge.**
- Recap the pen properly after each use in order to protect it from damage.
- 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. Return the pen to the refrigerator immediately after injecting the dose.
- Do not transfer the contents of the pen into another syringe.
- The pen can be used for 28 days from the first use.
- After the 28-day period, the pen should be discarded even if it still contains solution.
- **If you forgot to take the medicine at the regular time, take it as soon as you can, on the same day.**
- **Do not inject more than once at the same day.**
- **If you have injected an overdose,** or if a child has accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Transient side effects have been reported, including nausea, vomiting, weakness and dizziness, pain, hypercalcemia, hypotension and particularly during transition from a lying to standing position.
- Adhere to the treatment as recommended by the doctor.
- You should complete the full course of treatment as recommended by your doctor. Even if there is an improvement in your health, do not discontinue treatment with 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.

Contact your doctor if:

- You are experiencing side effects that might indicate high blood calcium levels, such as: nausea, vomiting, constipation, fatigue or muscle weakness (rare).

Common side effects:

- Nausea
- Headache
- Dizziness
- Gastritis
- Insomnia
- Shortness of breath
- Anxiety
- Herpes Zoster
- Pneumonia
- Pain
- Joint pain
- Low blood pressure during transition from a lying to standing position, which includes dizziness and irregular heartbeat
- **Teriparatide Teva** may transiently increase blood calcium levels
- **Teriparatide Teva** may increase blood uric acid concentration

Additional side effects:

- One or more of the following side effects may occur at the injection site: redness, swelling, pain, itching, a few drops of blood, bruising. These side effects are usually mild and disappear after a short time
- An allergic reaction (drug hypersensitivity) which might cause an anaphylactic reaction, rash, difficulties swallowing or breathing, swelling of the lips, face, throat or tongue (angioedema)
- Muscle spasms or pain (such as in the legs or back)
- Chest pain

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.
- Keep refrigerated (2°C-8°C).
- Do not freeze. Do not use the medicine that has been frozen.
- The pen can be used within 28 days from the first injection.

- Do not use the pen if the solution appears cloudy, 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, mannitol, hydrochloric acid, sodium hydroxide, water for injections.

What the medicine looks like and contents of the pack:

- A pre-filled pen containing clear, transparent solution.
- The pen is intended for multiple administrations and must be disposed of upon completion of use.
- Each 2.4 ml syringe contains 600 mcg teriparatide, sufficient for 28 days of treatment.
- Each package contains 1 or 3 pre-filled pens. Not all pack sizes may be marketed.
- **The Teriparatide Teva package does not include needles. 29G or 31G injection needles can be used.**

Registration holder's name and address: Abic Marketing Ltd., POB 8077, Netanya.

Manufacturer's name and address: Teva Pharmaceutical Industries POB 3190, Petach Tikva.

This leaflet dated February 2020 is in accordance with the format determined by the Ministry of Health and its content is consistent with Forteo leaflet, which was reviewed and approved by the Ministry of Health in April 2014.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
163-24-35333-00