PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a physician's prescription only

Teriparatide Kamada

Solution for subcutaneous injection

Active ingredient and its quantity: teriparatide 250 microgram/mL
Each injected dose contains:
teriparatide 20 microgram

Inactive ingredients: see Section 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, contact your doctor or pharmacist.
Also read the User Manual of the Teriparatide Kamada pen.
This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them even if their illness seems to be the same as yours.

Teriparatide Kamada is a bio-similar product. For more information on bio-similar products, please contact the Ministry of Health website: https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx

1. WHAT IS THIS MEDICINE INTENDED FOR?

- Treatment of men and postmenopausal women who are suffering from osteoporosis and are at high risk of developing fractures.
- Treatment of osteoporosis associated with corticosteroid therapy in men and women at increased risk for fractures.
- Teriparatide Kamada 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 preparation 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 regarding the use of this medicine:

- Bone cancer (osteosarcoma) has been reported rarely in patients who had been taking teriparatide. In people, osteosarcoma is a serious but rare cancer. It is not known if people who take Teriparatide Kamada have a higher chance of getting osteosarcoma.
- The duration of treatment is limited to two years over your lifetime.

Before starting treatment with Teriparatide Kamada, 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 kidney/urinary tract dysfunction, kidney or urinary stones or high levels of calcium in the urine.
- you suffer from Paget's disease or other bone disease.
- you have bone cancer.
- you have trouble injecting the medicine yourself and do not have someone who can help you.
- you are a child or young adult whose bones 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 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 whose bones are still growing.

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

Drug interactions
If you are taking or have recently taken any other medicines, including non-prescription medications and nutritional supplements, inform your doctor or pharmacist. You should tell your doctor or pharmacist especially if you are taking or planning to take:

- Digoxin – Teriparatide Kamada may increase calcium levels. Therefore, Teriparatide Kamada should be taken more carefully in patients taking digoxin.

Use of this medicine and food:
You can inject at any time of the day, regardless of mealtimes or drinks.

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 treatment of Teriparatide Kamada.

Breastfeeding
It is not known whether teriparatide is excreted in breast milk, whether it affects breast milk production, or has effects on the breastfed infant. Do not breastfeed during Teriparatide Kamada treatment.

Driving and using machines:
The use of this medicine may cause dizziness (see section "Side effects"). In case you experience this, please avoid driving or operating machinery.

3. HOW TO USE THIS MEDICINE?

- Always use the preparation according to the doctor's instructions. You must check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this preparation.
- The dosage and manner of treatment will be determined only by your doctor. The standard dose is usually one subcutaneous injection per day, in the thigh or lower stomach area. Consult your doctor on 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 is to be taken at specific time intervals as determined by your attending doctor.
- Teriparatide Kamada is intended for subcutaneous injection. Before using Teriparatide Kamada, carefully read the user manual enclosed in the package. Use the pen injector according to the detailed instructions in the manual.
- Teriparatide Kamada's injection fluid should look clear and colorless. Do not use Teriparatide Kamada if it has particles in it, or if it is cloudy or colored.
- You can inject Teriparatide Kamada at any time of the day. To help you remember, it is recommended to inject it at about the same time each day.
- Before you try to inject Teriparatide Kamada to yourself, the doctor should teach you how to use the Teriparatide Kamada delivery device to give your injection the right way.
- At the beginning of treatment, administer the medicine where you can sit or lie down, in case you feel orthostatic hypotension in the transition from lying down to standing, which is characterized by dizziness, weakness, a feeling of fainting and rapid heartbeats.
- The dose should be injected immediately after you take the pen injector out of the refrigerator.
- After each use, safely remove the needle, recap the delivery device, 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 the wrong dose of Teriparatide Kamada. Contact your doctor if you do not have pen needles to use with your injection pen.
- The pen should be used for 28 days from the first use.
- After a period of 28 days, the pen should be discarded even if it has solution in it.
- Teriparatide Kamada has enough medicine for 28 days. Teriparatide Kamada is intended to give a 20 microgram dose of medicine each day. Do not inject all the medicine in the Teriparatide Kamada at once.
- Follow your doctor's instructions for other ways you can treat your osteoporosis, such as exercise, nutrition, 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 taking Teriparatide Kamada.

If you have accidentally injected a higher dose, or if a child has swallowed the medicine, proceed immediately to a doctor or a hospital's Emergency Room and bring the package of the medicine with you. Side effects have been reported of nausea, vomiting, weakness, dizziness, headache, orthostatic hypotension during the transition from lying down to standing. There may also be an increase in the level of calcium in the blood (hypercalcemia).

If you forgot or if you can't take the medicine on time, take it as soon as you can that day. **Do not inject Teriparatide Kamada more than once a day.** Continue 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 each time you take your medicine. Wear glasses if you need them.
If you have any questions regarding the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Teriparatide Kamada may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Teriparatide Kamada can cause serious side effects:

- Osteosarcoma: Cases of osteosarcoma (bone cancer) and bone tumor have been rarely reported.
- Orthostatic hypotension during the transition from lying down to standing. There are some users who 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 Kamada and goes away within a few hours. For the first few doses, take your Teriparatide Kamada injection 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 Kamda and call your doctor.
- Increased calcium in your blood.

Tell your doctor if you are experiencing 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 trials with postmenopausal women and 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 disorders, gastrointestinal disorders

Musculoskeletal:
Arthralgia, leg cramps

Nervous System:
Dizziness, vertigo, insomnia, depression

Respiratory System:
Rhinitis, cough increased, pharyngitis, dyspnea, pneumonia

Skin:
Rash, sweating

Side effects observed in trials with patients with osteoporosis associated with corticosteroid therapy:

- Nausea
- Gastritis
- Pneumonia
- Dyspnea
- Insomnia
- Anxiety
- Herpes zoster

Side effects with an 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 that were reported since market introduction, but not necessarily causally related to teriparatide therapy, include the following:

- Allergic reactions: anaphylactic reactions, drug hypersensitivity, angioedema, urticaria
- Laboratory results: an increase in the level of uric acid in the blood
- Respiratory system: acute dyspnea, chest pain
- Musculoskeletal: muscle spasms of the leg or back
- Other: injection site reactions including injection site pain, swelling and bruising; facial edema

If a side effect occurs, if any of the side effects gets worse, or if you are suffering from a side effect that has not been mentioned in this leaflet, consult a doctor.

Reporting of side effects
Side effects may be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" that can be found on the Home Page of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link:
https://sideeffects.health.gov.il
Additionally, you may also report to Kamada Ltd. to the email address:
pharmacovigilance@kamada.com

5. HOW TO STORE THIS MEDICINE?

- **Avoid poisoning!** This medicine and all other medicines must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiration date (exp. date) appearing on the package. The expiration date refers to the last day of that month.
- Store in the refrigerator at a temperature between 2°C-8°C at all times. Do not freeze. Do not use the product if it has been frozen.
- The pen should be covered with pen cap to protect the cartridge from physical damage and light.
- The pen may be used immediately after removal from refrigerator.
- After first use store in the refrigerator (2°C-8°C) and use within 28 days. The pen is to be discarded 28 days after first use. During the use period, the time out of the refrigerator should be minimized; the dose may be delivered immediately following the removal from the refrigerator.
- Do not use the pen if the solution appears cloudy, with color or has particles in it.
- Do not throw away any medicines via wastewater or household waste. Ask your 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, the medicine also contains:
mannitol, metacresol, glacial acetic acid, sodium acetate, and water for injections.

What the medicine looks like and the contents of the package:

- A prefilled injector pen containing a clear colorless solution.
- The pen is intended for multiple administrations, for a single patient use and must be disposed of upon completion of use.
- Each 2.48 ml syringe contains 620 microgram teriparatide and is sufficient for 28 days of treatment.
- The package contains one pen.

License holder and address: Kamada Ltd., Beit Kama

Manufacturer's name and address: Alvogen Inc., Morristown, NJ, USA

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The drug registration number in the National Drug Registry in the Ministry of Health: 170-21-36517