Package leaflet: Information for the user

Tetridar®20 micrograms/80 microlitres Solution for Injection in pre-filled pen
teriparatide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tetridar® is and what it is used for

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

Tetridar® is used to treat osteoporosis in adults. Osteoporosis is a disease that causes your bones to become thin and fragile. This disease is especially common in women after the menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

2. What you need to know before you use Tetridar®

Do not use Tetridar®:
- if you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from high calcium levels (pre-existing hypercalcaemia).
- if you suffer from serious kidney problems.
- if you have ever been diagnosed with bone cancer or other cancers that have spread (metastasised) to your bones.
- if you have certain bone diseases. If you have a bone disease, tell your doctor.
- if you have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget's disease of bone (disease with abnormal bone changes). If you are not sure, ask your doctor.
- if you have had radiation therapy involving your bones.
- if you are pregnant or breast-feeding.

Warnings and precautions
Tetridar® may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using Tetridar®:
- if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.

- if you suffer from kidney stones or have a history of kidney stones.
- if you suffer from kidney problems (moderate renal impairment).

Some patients get dizzy or get a fast heartbeat after the first few doses. For the first doses, inject Tetridar® where you can sit or lie down right away if you get dizzy.

The recommended treatment time of 24 months should not be exceeded.

Tetridar® should not be used in growing adults.

Children and adolescents
Tetridar® should not be used in children and adolescents (less than 18 years).

Other medicines and Tetridar®
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because occasionally they may interact (e.g. digoxin/digitalis, a medicine used to treat heart disease).

Pregnancy, breast-feeding and fertility
Do not use Tetridar® if you are pregnant or breast-feeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of Tetridar®. If you become pregnant, Tetridar® should be discontinued. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Some patients may feel dizzy after injecting Tetridar®. If you feel dizzy you should not drive or use machines until you feel better.

Important information about some of the ingredients of Tetridar®:
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to use Tetridar®

Always use this medicine exactly as your doctor has told you to. 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 take your medicine, inject it at about the same time each day.

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

Tetridar® can be injected at meal times.

Read the user manual booklet, which is included in the carton for instructions on how to use the Tetridar® pen.

Injection needles are not included with the pen. Becton, Dickinson and Company pen needles 29 to 31 gauge (diameter 0.25-0.33 mm) and 12.7, 8 or 5 mm length can be used.

You should take your Tetridar® injection shortly after you take the pen out of the refrigerator as described in the user manual. 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 Tetridar® pen with others.

Your doctor may advise you to take Tetridar® with calcium and vitamin D. Your doctor will tell you how much you should take each day.

Tetridar® can be given with or without food.

If you use more Tetridar® than you should
If, by mistake, you have used more Tetridar® than you should, contact your doctor or pharmacist. The effects of overdose that might be expected include nausea, vomiting, dizziness, and headache.

If you forget or cannot take Tetridar® at your usual time, take it as soon as possible on that day. Do not take a double dose to make up for a forgotten dose. Do not take more than one injection in the same day. Do not try to make up for a missed dose.

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The most common side effects are pain in limb (frequency is very common, may affect more than 1 in 10 people) and feeling sick, headache and dizziness (frequency is common).If you become dizzy (light-headed) after your injection, you should sit or lie down until you feel better. If you do not feel better, you should call a doctor before you continue treatment. Cases of fainting have been reported in association with teriparatide use.

If you experience discomfort such as redness of the skin, pain, swelling, itching, bruising or minor bleeding around the area of the injection (frequency is common), this should clear up in a few days or weeks. Otherwise tell your doctor as soon as possible.

Some patients may have experienced allergic reactions soon after injection, consisting of breathlessness, swelling of the face, rash and chest pain (frequency is rare). In rare cases, serious and potentially life-threatening allergic reactions including anaphylaxis can occur. If you experience any of these symptoms, **STOP taking Tetridar® and contact your doctor IMMEDIATELY.**

Other side effects include:
Common: may affect up to 1 in 10 people
- increase in blood cholesterol levels
- depression
- neuralgic pain in the leg
- feeling faint
- irregular heart beats
- breathlessness
- increased sweating
- muscle cramps
- loss of energy
- tiredness

- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- being sick (vomiting)
- a hernia of the tube that carries food to your stomach
- low haemoglobin or red blood cell count (anaemia).

Uncommon: may affect up to 1 in 100 people
- increased heart rate
- abnormal heart sound
- shortness of breath
- haemorrhoids (piles)
- accidental loss or leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some patients have experienced severe back cramps or pain which lead to hospitalisation.
- increase in blood calcium level
- increase in blood uric acid level
- increase in an enzyme called alkaline phosphatase.

Rare: may affect up to 1 in 1,000 people
- reduced kidney function, including renal failure
- swelling, mainly in the hands, feet and legs.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tetridar®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pen after EXP. The expiry date refers to the last day of that month.

Tetridar® should be stored in a refrigerator (2°C to 8°C) at all times. You can use Tetridar® for up to 28 days after the first injection, as long as the pen is stored in a refrigerator (2°C to 8°C).

Do not freeze Tetridar®. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use Tetridar® if it is, or has been, frozen.

Each pen should be properly disposed of after 28 days, even if it is not completely empty.

Tetridar® contains a clear and colourless solution. Do not use Tetridar® if solid particles appear or if the solution is cloudy or coloured.

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 to protect the environment.

6. Contents of the pack and other information

What Tetridar® contains

- The active substance is teriparatide. One pre-filled pen of 2.4 mL contains 600 micrograms of teriparatide (corresponding to 250 micrograms per mL).
- The other ingredients are glacial acetic acid, sodium acetate trihydrate, mannitol, metacresol, and water for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added for pH adjustment.

What Tetridar® looks like and contents of the pack

Tetridar® is a colourless and clear solution. It is supplied in a cartridge contained in a pre-filled disposable pen. Each pen contains 2.4 mL of solution enough for 28 doses. The pens are available in cartons containing one or three pens. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

Manufacturer

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)
Prilaz baruna Filipovića 25, Zagreb, 10000
Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

Cyprus	Tetridar® 20 micrograms/80 microliters ενέσιμο διάλυμα σε προγεμισμένη συσκευή τύπου
Denmark	Tetridar®
Germany	Tetridar® 20 Mikrogramm/80 Mikroliter Injektionslösung
Greece	Tetridar® 20 micrograms/80 microliters ενέσιμο διάλυμα σε προγεμισμένη συσκευή τύπου πένας
Ireland	Tetridar® 20 micrograms/80 microlitres Solution for Injection in pre-filled pen
Malta	Tetridar® 20 micrograms/80 microlitres Solution for Injection in pre-filled pen
Spain	Tetridar®20 microgramos/80 microlitros solución inyectable en pluma precargada

This leaflet was last revised in February 2022.