

TERISUN

(Teriparatide 250mcg/ml Solution for Injection, 2.4ml Pre-Filled Pen)

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What **TERISUN** is used for

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

TERISUN 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.

How **TERISUN** works

TERISUN contains a synthetic form of natural human hormone called parathyroid hormone (PTH). It works by causing the body to build new bone and by increasing bone strength and density (thickness).

Before you use **TERISUN**

- When you must not use it

Do not use **TERISUN**

- if you are allergic to teriparatide or any of the other ingredients of this medicine.
- if you have high calcium levels in blood (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 (metastasized) to your bones.
- 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.

- Before you start to use it

TERISUN may cause an increase in the amount of calcium in your blood or urine. Talk to your doctor or pharmacist before or while using **TERISUN**:

- 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 **TERISUN** where you can sit or lie down right away if you get dizzy.

The recommended treatment time of 24 months should not be exceeded. **TERISUN** should not be used in growing adults.

If you are not sure if any of the above applies to you, talk to your doctor before taking **TERISUN** to see if this medicine is suitable for you.

Children and adolescents

TERISUN should not be used in children and adolescents (less than 18 years).

Pregnancy and breast-feeding

Do not use **TERISUN** 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 **TERISUN**. If you become pregnant, **TERISUN** should be discontinued. Ask your doctor or pharmacist for advice before taking any medicine.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because occasionally they may interact.

Tell your doctor if you are taking:

- Digoxin/digitalis (a medicine used to treat heart disease).

How to use **TERISUN**

- How much to use

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 (in 80 microliters) given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen.

To help you remember to use your medicine, inject it at about the same time each day.

- When to use it

TERISUN can be injected at about the same time each day.

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

Your doctor may advise you to use **TERISUN** with calcium and vitamin D.

Your doctor will tell you how much you should use each day.

TERISUN can be given with or without food.

- How long to use it.

Inject **TERISUN** each day for as long as your doctor prescribes it for you.

The total duration of treatment with **TERISUN** should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

- If you forget to use it

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

- If you use too much (overdose)

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

While you are using TERISUN

- Things you must do

If you are considering stopping **TERISUN** treatment, please discuss this with your doctor.

Your doctor will advise you and decide how long you should be treated with **TERISUN**.

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

You should use your **TERISUN** 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.

No needles are supplied with the product. The device can be used with pen needles (31G, 5mm). A new, sterile needle must be used for every injection. Never store your pen with the needle attached.

- Things you must not do

Do not use more than the recommended dose for your condition. Your doctor will want to discuss your treatment from time to time.

If you are considering stopping **TERISUN** treatment, please discuss this with your doctor.

Never share your **TERISUN** pen with others.

TERISUN should not be used if the solution is cloudy, coloured or contains particles.

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

- Things to be careful of

Driving and using machines

Some patients may feel dizzy after injecting **TERISUN**. If you feel dizzy you should not drive or use machines until you feel better

Talk to your doctor for further information.

Side Effects

Like all medicines, **TERISUN** 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.

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 heartbeats
- 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
- piles (haemorrhoids)
- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TERISUN

- Storage

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.

TERISUN should be stored in a refrigerator (2°C to 8°C) at all times. You can use **TERISUN** 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 **TERISUN**. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use **TERISUN** if it is, or has been, frozen.

Store in original package (i.e., outer carton) in order to protect from light.

- Disposal

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

Product Description

- What it looks like

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

TERISUN 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 pen.

- **Ingredients**

- *Active ingredient*

Teriparatide. Each dose of 80 microliters contains 20 micrograms of teriparatide. Each pre-filled pen of 2.4 ml contains 600 micrograms of teriparatide (corresponding to 250 micrograms per ml).

- *Inactive ingredients*

The other ingredients are:

Mannitol

Glacial acetic acid

Sodium acetate anhydrous

Metacresol

Sodium hydroxide for pH adjustment

Hydrochloric acid for pH adjustment

Water for Injection

- MAL Number:

MALXXXXXXXXXX

Manufacturer

Sun Pharmaceutical Industries Ltd.

Halol Baroda Highway

Halol – 389 350, Gujarat

India

Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate,

08000 Sungai Petani, Kedah, Malaysia.

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