

KAULIV Solution for Injection

Teriparatide 20 micrograms in 80 microliters

What is in the leaflet

1. What KAULIV is used for
2. How KAULIV works
3. Before you use KAULIV
4. How to use KAULIV
5. While you are using it
6. Side effects
7. Storage and disposal of KAULIV
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of Revision
12. Serial Number

What KAULIV is used for

KAULIV 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 people receiving corticosteroids.

How KAULIV works

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

Before you use KAULIV

- When you must not use it

Do not use KAULIV

- If you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section "Ingredients").
- 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 (metastasized) 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.

Pregnancy and lactation

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

- Before you start to use it

KAULIV may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using KAULIV:

- 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 are suffering from kidney or urinary tract stones or have a history of kidney or urinary tract stones.
- If you suffer from kidney problems (moderate renal impairment).

- 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 (e.g. digoxin/digitalis, a medicine used to treat heart disease).

How to use KAULIV

- How much to use

Always use this medicine exactly as your doctor has told you. 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.

Children and adolescents

KAULIV should not be used in children or in young adults if their bones have not finished growing (open epiphyses).

KAULIV should not be used in children.

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

- When to use it

Use as directed by your doctor or pharmacist daily to help you remember to take your medicine, inject it at about the same time each day.

KAULIV can be given with or without food.

Instructions for use

KAULIV cartridge are designed to be used only with the KAULIV multidose pen and compatible pen needles. The pen

and injection needles are not included with KAULIV cartridge.

Before the first use, insert the cartridge into the pen (which is supplied separately). For the correct use of this medicine, it is very important to closely follow the detailed Instruction for Use (IFU) of your pen which are provided with the pen.

Injection needles are not included with the pen. Use with pen needles 32G 4mm.

You should take your KAULIV injection shortly after you take the pen out of the refrigerator as described in the user manual. Put the pen back into refrigerator immediately after you have used it. Do not remove the cartridge from the pen after each use (see also section “Storage and Disposal of KAULIV”).

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 KAULIV pen with others.

Do not use your KAULIV pen to inject any other medicine (e.g. insulin). The pen is customized for use with KAULIV only. Do not refill the cartridge. Do not transfer the medicine into a syringe.

- How long to use it

Inject KAULIV each day for as long as your doctor prescribes it for you. The total duration of treatment with KAULIV 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 take KAULIV 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 use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The effects of overdose that might be expected include nausea, vomiting, dizziness, and headache.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking KAULIV.

Tell your doctor immediately if you become pregnant while taking this medication.

If you are about to have any blood tests, tell your doctor that you are using KAULIV. This medicine can cause small, temporary increases in blood calcium levels. If blood samples are taken, this needs to be done at least 16 hours after the last KAULIV injection.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

If you are considering stopping KAULIV treatment, please discuss this with your doctor. Your doctor will advise you and decide how

long you should be treated with KAULIV.

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

- Things to be careful of

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

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

Driving and using machines

Some people may feel dizzy after injecting KAULIV. If you feel dizzy you should not drive or use machines until you feel better.

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 people 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 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 people have experienced severe back cramps or pain which lead to hospitalization
- 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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

KAULIV

- Storage

Keep out of the reach and sight of children.

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

KAULIV should be stored in a refrigerator (2°C to 8°C) at all times. Keep the cartridge in the outer carton in order to protect from light. The cartridge within the pen can additionally be placed in the pouch supplied with the pen in order to protect from light. You can use KAULIV for up to 28 days after the first injection, as long as the cartridge within the pen is stored in a refrigerator (2°C to 8°C).

Do not freeze KAULIV. Avoid placing the cartridge close to the

ice compartment of the refrigerator to prevent freezing. Do not use KAULIV if it is, or has been, frozen.

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

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

Do not store the injection device with the needle attached.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Product Description

- What it looks like

KAULIV is a colourless and clear solution. It is supplied in a cartridge. Each cartridge contains 3mL of solution enough for 28 doses.

- Ingredients

Active ingredient(s): Teriparatide. Each mL of the solution for injection contains 250 micrograms of teriparatide.

Inactive ingredients: D-Mannitol, Metacresol, Acetic Acid Glacial, Sodium Acetate Anhydrous, Water for Injection, Diluted Hydrochloric Acid (for pH adjustment) and Sodium Hydroxide (for pH adjustment).

- MAL number
MAL24096023AZ

Manufacturer and Released by:

OneSource Specialty Pharma
Limited,
D1 Plot No 2, A Taluk,
Doddaballapur, Karnataka,
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Product Registration Holder

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