

OSTEOCAP CAPSULE

Calcitriol (0.25 mcg)

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What Osteocap Capsule is used for

Osteocap Capsule is used to treat the following:

- Post-menopausal osteoporosis (weaken bones in women after menopause).
- Renal osteodystrophy (bone disease with severe kidney failure and undergoing dialysis).
- Hypoparathyroidism (decreased function of the parathyroid gland).
- Rickets due to vitamin-D resistant or vitamin-D dependent

How Osteocap Capsule works

Osteocap Capsule contains calcitriol which is an active form of Vitamin D3.

Osteocap Capsule works by enabling your body to absorb more calcium from your diet. This helps to form healthy bones and reduce bone damage.

Before you use Osteocap Capsule

- *When you must not use it*

Do not use Osteocap Capsule if;

- You are allergic to calcitriol or any other ingredients of this medicine (listed in Product Description).
- You have any disease associated with an increase blood calcium level (hypercalcemia).
- You have Vitamin D toxicity

- *Before you start to use it*

Pregnancy and Lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breastfeeding before using any medicine.

You must tell your doctor or pharmacist if you:

- Have kidney failure.
- Just undergone surgery

- *Taking other medicines*

Tell your doctor if you are taking any other medicines that you buy with or without prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other supplements containing vitamin D such as ergocalciferol, calcium and phosphate.
- Diuretics (used to treat high blood pressure) e.g: thiazide.
- Digitalis (used to treat heart disease).
- Antacids containing magnesium, (used to treat indigestion).
- Phenytoin or phenobarbital (used to treat epilepsy).
- Colestyramine (used to treat high levels of cholesterol in your blood).

How to use Osteocap Capsule

Use as directed by your doctor or pharmacist.

- *How much to use*

- Calcitriol therapy should always be started at lowest possible dose and should not be increased without careful monitoring of calcium level in the blood.

- While you are taking Osteocap, your doctor will want you to have regular blood tests to check that the level of calcium in your blood does not get too high.

- Because of improved calcium absorption from the gastrointestinal tract, some people on calcitriol may be maintained on a lower calcium intake.

- If you tend to develop hypercalcemia, you may require only low doses of calcium or no supplementation at all. The total daily calcium intake (i.e. from food and medicines) should average approximately 800 mg and should not exceed 1000 mg.

• **Post-menopausal osteoporosis**

The usual dose is 1 capsule twice a day.

• **Renal osteodystrophy**

The starting dose is 1 capsule once a day. People with normal or only slightly reduced serum calcium levels, doses of 1 capsule every other day are sufficient. If no satisfactory response is observed within 2-4 weeks, the dosage may be increased by 1 capsule once a day for 2- to 4- week intervals. Most people respond to between 2 and 4 capsules once a day.

• **Hypoparathyroidism and Rickets**

The starting dose is 1 capsule in the morning. The dose may be increase at 2 to 4 week intervals.

- **Elderly:** No specific dosage modifications are required in elderly. The general recommendations for monitoring calcium and creatinine level in blood.

- *When to use it*

Osteocap Capsule to be taken orally with or without food

- *How long to use it*

Take Osteocap Capsule for as long as your doctor recommends.

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- If you forget to use it

- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose.
- Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

- Vitamin D intoxication can occur after excessive intake of Vitamin D, that leads to the development of hypercalcaemia (high calcium level in blood).
- You may experience symptoms of eating disorder, vomiting, headache, constipation, weakness or muscle weakness, fever with thirst, excessive urination and urinary tract infection.
- Discontinue use and contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Osteocap Capsule

- Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking Osteocap Capsule.
- Tell your doctor immediately if you become pregnant while taking Osteocap Capsule.

- Things you must not do

- Do not stop taking Osteocap Capsule abruptly or change the dose without consulting with your doctor. Your doctor will advise the best way to reduce the dose of Osteocap Capsule slowly before stopping completely.
- Do not use any new medicines without consulting your doctor or pharmacist.
- Do not give Osteocap Capsule to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- If you are with normal kidney function who takes calcitriol, you should avoid dehydration by consuming adequate fluid intake.
- Be careful driving or operating machinery until you know how Osteocap affects you.

Side Effects

- Like all medicines, Osteocap Capsule can cause side effects, although not everybody gets them.
- This product may cause eating disorder, vomiting, headache, constipation, weakness or muscle weakness, fever with thirst, excessive urination and urinary tract infection.
- Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of Osteocap Capsule

- Storage

Store below 30°C in a dry place, away from direct sunlight.
Keep out of reach of children.

- 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 to protect the environment.

Product Description

- What it looks like

Red and white, oval shaped, opaque soft gelatin capsule.

- Ingredients

- Active Ingredient
Calcitriol

- Inactive Ingredients

Butylated Hydroxyanisole, Iron oxide yellow, Iron Oxide Red, Titanium Dioxide, Glycerin, fractionated coconut oil, Sorbitol 70% solution, Gelatin, Purified Water, BHT (Butylated Hydroxytoluene).

- MAL number

MAL05092239X

Manufacturer

Mega Lifesciences Public Company Limited
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Product Registration Holder

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