

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 10/2019

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: EDIROL Capsules 0.5mcg

Active ingredient: Eldecalcitol

Dosage form: opaque brownish white capsule (diameter: 6.6mm)

Print on wrapping: エデイロール 0.5 μ g



Effects of this medicine

This activated vitamin D₃ derivative enhances digestive absorption of calcium and improves bone metabolic turnover. As the result, it increases bone mineral density, makes bones strong and prevents fractures caused by osteoporosis. It is usually used to treat osteoporosis.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reaction (itch, rash etc.) to any medicines.
If you are a patient with hypercalcemia, malignancy, primary hyperparathyroidism.
- If you have or ever had urinary calculus. If you have or ever had urinary calculus.
- If you are a patient with renal function disorder, hepatic function disorder.
- If you are pregnant, possibly pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- The dosage of this medicine is adjusted under a fully controlled condition of serum calcium level.
In general, for adults, take 0.75 mcg of the active ingredient once a day. It should be decreased according to your symptoms. 1 capsule contains 0.5 mcg of the active ingredient. Strictly follow the instructions.
- If you missed a dose, skip the missed dose and continue your regular dosing schedule. However, you should never take two doses at one time.
- If you accidentally took more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Fetal malformation and lacteal transfer has been reported in animal experiments. If you have a possibility of getting pregnant, avoid pregnancy while you are taking the medicine.
- If you take a large amount of calcium or vitamin D contained in OTC medicine or food while taking this medicine, you may have a higher risk of side effects. Check with your doctor about it beforehand.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include hypercalcemia. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- dry mouth, excess intake of water, nausea, vomiting, increased urinary volume, unable to concentrate [hypercalcemia]
- general malaise, edema, easy fatigability, decreased consciousness, headache, swollen eyes, breathing difficulty, decreased urinary volume [acute renal failure]
- severe low-back/back pain, abdominal pain, bloody urine [urinary calculus]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store in a covered container, at room temperature (1 to 30°C), away from light and moisture.
- Discard the remainder. Do not store them. Ask the pharmacist or healthcare facility how to discard them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.