

Package leaflet: Information for the patient

Ostrong Tablets

Calcium Hydrogen Phosphate 600 mg and Cholecalciferol (Vitamin D3) 500 I.U.

Read all of this leaflet carefully before you start taking 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.

What is in this leaflet

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2. What you need to know before you take Ostrong
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1. What Ostrong is and what it is used for

This medicine contains two active substances calcium and cholecalciferol (also known as vitamin D3). Calcium is an important constituent of bone and vitamin D3 helps the absorption of calcium by the intestine and its deposition in the bones.

This medicine is used:

- In the correction of calcium and vitamin D deficiencies in the elderly.
- In combination with osteoporosis treatments where calcium and vitamin D levels are too low or where there is a high risk of them being too low.

2. What you need to know before you take Ostrong

Do not take Ostrong:

- If you are allergic (hypersensitive) to calcium, vitamin D or any of the other ingredients of this medicine (listed in section 6).
- If you have an abnormally high levels of calcium in your blood (hypercalcemia) and/or excessive loss of calcium in the urine (hypercalciuria).
- If you have a condition that could lead to hypercalcemia and/or hypercalciuria (e.g. overactive parathyroid glands, a disease of the bone marrow (myeloma), a malignant bone tumor (bone metastases)).
- If you have serious kidney problems.
- If you have kidney stones or calcium deposits in your kidneys (nephrocalcinosis).
- If you have abnormally high levels of vitamin D (hypervitaminosis D).
- If you are less than 12 years of age.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Ostrong:

- If you are taking this medicine for a long time. Your doctor will regularly monitor the quantity of calcium in your blood (calcemia). This monitoring is particularly important in the elderly and where treatment is being taken at the same time as cardiac glycosides (e.g. digoxin) or diuretics (water tablets).
- If you have had kidney stones.
- If you are suffering from an immune disorder (sarcoidosis), as the amount of calcium in your blood and urine must be checked.
- If you are immobile and are suffering from reduced bone mass (osteoporosis). This may increase the level of calcium in your blood too much which can cause side effects.
- If you are taking other medicines containing vitamin D3 or calcium. This may increase the level of calcium in your blood too much which can cause side effects.

Children and adolescents:

This medicine is not recommended for children under 12 years old.

Other medicines and Ostrong:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, especially:

- Thiazide diuretics (medicines used to treat high blood pressure), as they may increase the amount of calcium in your blood.
- Oral steroids (such as cortisone), as they may reduce the amount of calcium in your blood.
- Orlistat (a medicine used to treat obesity), cholestyramine (used to treat high blood cholesterol levels), laxatives such as paraffin oil, as they may reduce the amount of vitamin D3 you absorb.
- Phenytoin (a medicine for epilepsy) and barbiturates (medicines which help you sleep), as they may make the vitamin D3 less effective.
- Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects if you take too much calcium.
- Tetracycline antibiotics, as the amount absorbed may be reduced. They should be taken at least 3 hours before or after Ostrong.
- Estramustin (a medicine used in chemotherapy), thyroid hormones or medicines containing iron, zinc or strontium, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after Ostrong.
- Bisphosphonates (a treatment for bone conditions), fluoride or fluoroquinolones (a type of antibiotic), as the amount absorbed may be reduced. They should be taken at least 3 hours before or after Ostrong.
- Other medicines containing calcium or vitamin D while you are taking Ostrong. This may increase the level of calcium in your blood.

Ostrong with food and drinks:

In the two hours before taking this medicine, you should avoid eating food that contains oxalic acid (e.g. spinach and rhubarb), phosphate (especially from food additives) or phytic acid (wholegrain cereals), since these may reduce the absorption of calcium contained in your medicine.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine may be used during pregnancy, however your doctor will recommend the dosage based on your needs.

During breast-feeding you can use this medicine. However, as calcium and vitamin D3 passes into breast milk you have to check with your doctor first if your infant receives any other products containing vitamin D3.

Driving and using machines:

This medicine has no influence on your ability to drive or use machines.

Important information about some of the ingredients of Ostrong:

This medicine contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ostrong

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine:

- The usual dose is 1 tablet twice a day for adults and elderly (e.g. one in the morning and one in the evening).
- You should take the tablet with a large glass of water (200 ml).

If you take more Ostrong than you should

If you have taken more of this medicine than you should and experience any of the symptoms of overdose, stop taking it and immediately contact your doctor. Symptoms of overdose may include: anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones.

In the case of prolonged overdosage, calcium deposits may appear in blood vessels or body tissues.

In the case of major overdosage, cardiac arrest may occur.

If you forget to take Ostrong

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

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.

Stop taking this medicine and contact your doctor immediately if you experience any of the following:

- Swelling of face, lips and throat
- Sudden difficulty breathing
- Severe itching and/or rash (hives)
- Skin allergy

Tell your doctor promptly if you experience the following side effects, which may indicate that calcium levels in your blood or urine are too high:

- Anorexia, nausea (feeling sick), vomiting, headache, weakness, apathy and drowsiness
 - Thirst, dehydration, unintentional loss of urine throughout the day/night (urinary incontinence), abdominal pain, lack of bowel movement, irregular heart beat
- In addition, the following side effects may occur with the use of this medicine:
- Constipation
 - Diarrhea
 - Nausea (feeling sick) or vomiting
 - Stomach ache

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

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ostrong

- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ostrong contains

- The active substances are calcium and cholecalciferol (also known as vitamin D3).
- Each tablet contains elemental calcium 176 mg (as 600 mg calcium hydrogen phosphate) and cholecalciferol 500 I.U. equivalent to 0.0125 mg of vitamin D3.
- The other ingredients are lactose, magnesium stearate, microcrystalline cellulose, DL-alpha-tocopherol, sucrose, silicon dioxide, medium chain triglycerides, starch and sodium ascorbate crystalline.

What Ostrong looks like and contents of the pack

White oblong plain tablets.

Ostrong is available in boxes containing 60 tablets.

Marketing Authorisation Holder and Manufacturer

Pharmaline S.A.l. – Lebanon
P.O Box 90201.Jdeidet-El-Metn, Lebanon
Contact us: pharmaline@maliagroup.com
Website: www.pharmaline.com.lb

Ostrong tablets Reg. N° Lebanon : 405534/00

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.