Calciform D3®

Calcium+Cholecalciferol (1000mg+880 IU)

Effervescent tablets

PATIENT INFORMATION LEAFLET

1. DETERMINATION OF THE MEDICINAL PRODUCT

1.1 Name: CALCIFORM D3

1.2 Composition: Active ingredient: Calcium and Cholecalciferol (vitamin D3). **Excipients:** a-Tocopherol, Soya-bean oil, Gelatin, Sucrose, Maize starch, Citric acid anhydrous, Sodium hydrogen carbonate, Lactose monohydrate, Povidone, Saccharin sodium, Sodium cyclamate, Macrogol 6000, Orange juice flavour, Simethicone emulsion.

1.3 Pharmaceutical form: Effervescent tablet.

1.4 Content of active substance: One tablet contains: Calcium 1000 mg elemental as Calcium carbonate 2500 mg - Cholecalciferol (vitamin D3) 24,2 micrograms (880 IU) as Cholecalciferol concentrate (in powder form)

1.5 Description - Package: White polypropylene tubes closed with polyethylene caps with desiccant.
Available in packs of 30 and 60 effervescent tablets.

1.6 Pharmacotherapeutic group: Mineral supplements.

1.7 Marketing Authorisation Holder - Manufacturer: IASIS PHARMA HELLAS S.A, 137, Filis Ave. 13451 Kamatero Attica, Greece. Tel: + 30 210 2311031

2. THINGS THAT YOU SHOULD KNOW ABOUT THE MEDICINE PRESCRIBED BY YOUR DOCTOR

2.1 General Information: The medicine contains calcium and cholecalciferol (vitamin D3) as active substances and must provide to the organism calcium and vitamin D3. The combination of calcium and vitamin D3 is important for the maintenance of skeletal bones in good condition, because the vitamin D3 firstly improves the uptake of calcium administered, secondly achieves more appropriate distribution of calcium in the human body.

2.2 Indications: The medicine is used for the prevention and treatment of vitamin D and calcium deficiency in elderly people. Also, the medicine is used as a supplement of vitamin D and calcium and as an adjunct to specific osteoporosis treatment in patients who are likely to appear deficiency in vitamin D and calcium.

2.3 Contraindications: You should not take CALCIFORM D3 if you have ever had an allergic reaction to any of the ingredients (active substances or excipients).
Also, you should not take CALCIFORM D3, if you are suffering from diseases which lead to elevated levels of calcium in the blood (hypercalcemia) or urine (hypercalciuria), if you have kidney stones, or if you suffer from hypervitaminosis D.

2.4 Special warnings and precautions for use

2.4.1 Generally: During long-term treatment with CALCIFORM D3, calcium levels in the blood and renal function should be monitored. Such monitoring is particularly important in cases of elderly patients who are on concomitant treatment with diuretics or drugs of the class of cardiotonic glycosides and in patients with a high tendency to form kidney stones.
In cases of elevated calcium levels in the blood or signs of renal dysfunction, your doctor may reduce the dose or discontinue the treatment with CALCIFORM D3.
Vitamin D should be used with caution in patients with renal impairment and its effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, vitamin D in the form of cholecalciferol is not metabolised normally and therefore other forms of vitamin D should be used. If you suffer from renal impairment, please tell your doctor before using this medicine.
In the case of sarcoidosis, the medicine should be used with caution and a control of calcium levels in the blood and urine should be done. If you are suffering from sarcoidosis, please tell your doctor before using this medicine.
CALCIFORM D3 should be used with caution in immobilized patients with osteoporosis due to increased risk for elevated blood calcium levels.
The amount of vitamin D (880 IU) contained in each CALCIFORM D3 effervescent tablet should be taken into account when using other medicines containing vitamin D. Additional use of calcium or vitamin D should be initiated under close medical supervision. In such cases, the calcium levels in the blood and urine should be monitored frequently.
If you are taking other medications that contain calcium or vitamin D, please tell your doctor before using this medicine.

2.4.2 Use during pregnancy: During pregnancy, the medicine should only be taken after doctor's prescription and according to the dosage the doctor will set. CALCIFORM D3 (1000 mg/880 IU) is not suitable during pregnancy because of the content of vitamin D (> 600 IU).

2.4.3 Use during Lactation: Calcium and vitamin D pass into breast milk. This should be taken into consideration, particularly when administering additional vitamin D to the baby.
During the lactation period, the drug can only be taken after doctor's recommendation and according to the dosage the doctor will set.

2.4.4 Use in children: The drug is not intended for use in children.

2.4.5 Effects on ability to drive and use machines: There are no data on the drug's effect on ability to drive and use machines. However, it is unlikely that the drug has an effect on the ability to drive and use machines.

2.4.6 Special warnings about excipients: This medicine contains lactose and sucrose. Patients with rare hereditary intolerance in fructose, malabsorption of glucose-galactose or deficiency of sucrase / isomaltose, should not take this medicine.
The drug is containing vegetable fat which is partially hydrogenated soybean oil. If you have ever shown an allergy to peanuts or soya, do not use the medicine and inform your doctor accordingly.

2.5 Interaction with other medicinal products or other forms of interaction
Treatment with CALCIFORM D3 may affect therapy with other drugs or be affected by the treatment with other drugs taken simultaneously.

More specifically:
- In case of contemporary treatment with diuretics of the thiazide class, the risk of elevated levels of calcium in the blood Hypercalcemia) is higher, therefore regular monitoring of calcium levels in the blood should be done.
- In case of concomitant therapy with systemic corticosteroids may be necessary to increase the dose of the drug because the systemically administered corticosteroids reduce calcium absorption.
- In case of contemporary treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil the absorption of vitamin D may be reduced.
- In case of contemporary treatment with antibiotics of the tetracycline class, calcium may prevent the absorption of tetracyclines. Therefore, tetracycline preparations should be taken at least two hours before or four to six hours after ingestion.
- In case of contemporary treatment with of cardiac glycosides, the toxicity of cardiac glycosides may increase, because of hypercalcemia. Therefore, regular monitoring by your doctor, regarding the electrocardiogram and blood calcium levels, is recommended.
- In case you are in concomitant therapy with bisphosphonates or sodium fluoride, these drugs should be administered at least three hours prior to CALCIFORM D3 administration (because otherwise it is likely that their absorption will be reduced).
- In case of contemporary administration of oxalic acid (oxalic acid found in spinach and rhubarb) or phytic acid (phytic acid is found in whole grains), oxalic acid or phytic acid may inhibit the absorption of calcium. Therefore, CALCIFORM D3 should not be taken earlier than two hours since food rich in oxalic acid or phytic acid has been consumed.

Before using CALCIFORM D3, inform your doctor about all medicines you take.

2.6 Posology and method of administration

Your doctor will advise you on the dosage and duration of treatment, depending on your needs. The effervescent tablet must be dissolved in a glass of water and drunk immediately. If your doctor does not specify otherwise, the recommended dosage for adults and older people is 1 effervescent tablet daily. In patients with hepatic impairment, no dose adjustment is required. In patients with severe renal impairment, the medicine should not be used. You must follow the instructions of your doctor regarding the dosage and the duration of treatment.

2.7 Overdose-Treating

In case of overdose, call your doctor or Poison Control Centre.

Overdose can lead to hypervitaminosis and hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, kidney stones, and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification.

Treatment of Hypercalcaemia: The treatment with calcium and vitamin D must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, vitamin D and cardiac glycosides must also be discontinued.

Gastric emptying in patients with impaired consciousness is recommended. Rehydration, and, depending on the severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and central venous pressure should be monitored.

2.8 Undesirable effects

Togother with the desired action, any medicine may have some undesirable effects.The undesirable effects of using the medicine are listed below by category / organ system and frequency, and are as follows:

Metabolism and nutrition disorders: Uncommon (> 1/1.000 to <1/100): Hypercalcaemia and hypercalciuria.

Gastrointestinal Disorders: Rare (> 1/10.000, <1/1.000): Constipation, flatulence, nausea, abdominal pain and diarrhea.

Skin and subcutaneous tissue: Rare (> 1/10.000, <1/1.000): Pruritus, rash and urticaria.

In case of adverse reactions, contact your doctor.

2.9 What you should know in case you miss a dose

If you have to take the medicine continuously and miss a dose, you should take the missed dose as soon as possible. However, if it is almost time for your next dose, do not take the missed dose but continue as normal treatment.

2.10 Expiry date the product

The expiry date is stated on the outer and inner packaging. If the date has passed, do not use the product.

2.11 Special precautions for storage

Store the medicine at room temperature not exceeding 25 °C, in a dry place and close the tube well after taking an effervescent tablet.

2.12 Date of last revision of the leaflet: 19-05-2010

3. INFORMATION ON THE RATIONAL USE OF DRUGS

- This medicine was prescribed by your doctor for your specific health problem. You should not administer it to others or use it yourself for other health problems, without prior consent from your doctor.
- Inform immediately your doctor or pharmacist if a problem appears during the treatment.
- If you have any questions regarding the medicine that you are taking or you need further information on your health problem, do not hesitate to contact your doctor or pharmacist and ask for additional information.
- The medicine that was prescribed to you is safe and effective only when administered according to your doctor or pharmacist instructions.
- It is important for your safety and your health to read carefully all information regarding the medicine that was prescribed to you.
- Do not store medicines in bathroom closets since heat and humidity may alter them and render them hazardous for your health.
- Do not store medicines that have already expired or are no more useful to you.
- For more safety keep medicines in a secure place away from children.

4. MODE OF ADMINISTRATION

This medicine may only be administered with a doctor's prescription