

Calperos D₃[®]

Tablet to be sucked

IDENTIFICATION OF THE MEDICINAL PRODUCT

COMPOSITION

Cholecalciferol concentrat corresponding to cholecalciferol 400 IU
Calcium carbonate1250 mg
Corresponding to calcium element500 mg
Excipients: Xylitol, povidone (K30), levomenthol, aspartame, mint flavour, talc, magnesium stearate, lactose monohydrate, s.q.f. one tablet.

PHARMACEUTICAL FORM

Tablet to be sucked. Box of 60 tablets.

PHARMACOTHERAPEUTIC CLASS

VITAMIN D AND CALCIUM SUPPLEMENT (A: Gastro-intestinal system and Metabolism - Medicinal product acting on calcium levels).

NAME AND ADDRESS OF THE MARKETING COMPANY

BOUCHARA-RECORDATI Laboratories

68 Rue Marjolin

92 300 LEVALLOIS-PERRET - France

WHEN TO USE THIS MEDICINE?

This medicine is indicated in adults for:

- vitamin D and calcium deficiency in the elderly
- use in combination with treatments for osteoporosis when vitamin D and calcium intake are inadequate.

WARNING!

WHEN NOT TO USE THIS MEDICINE?

This medicine SHOULD NOT BE USED in the following circumstances:

- allergy to vitamin D or to any of the other tablet ingredients,
- abnormally high level of calcium in the blood (hypercalcaemia),
- excessive elimination of calcium in the urine (hypercalciuria),
- kidney stones (calcium lithiasis),
- prolonged periods of immobilisation accompanied by hypercalciuria and/or hypercalcaemia,
- because of the presence of aspartame, this medicine is contraindicated if the patient has phenylketonuria (a hereditary disease due to an enzyme deficiency).

IF IN DOUBT, YOU MUST ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE

SPECIAL WARNINGS

Because of the presence of lactose this medicine must not be used if the following concerns you: galactosemia, syndrom of malabsorption of glucose and galactose or deficiency of lactase (rare metabolic illnesses).

PRECAUTIONS FOR USE

Use this medicine WITH CAUTION if:

- this is long-term treatment: the quantity of calcium in the blood and eliminated in the urine (calciuria) should be monitored regularly. Depending on the results, your doctor may reduce or even stop your treatment.
- you are taking additional high doses of vitamin D and calcium, which should be carried out under strict medical supervision.
- you are taking bisphosphonate-based treatment or receiving treatment with a cycline antibiotic. It is recommended that you wait at least two hours between taking doses of these medicines and Calperos D₃.
- you have sarcoidosis or renal insufficiency.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

INTERACTIONS WITH OTHER MEDICINES AND OTHER INTERACTIONS

TO AVOID POSSIBLE INTERACTIONS BETWEEN DIFFERENT MEDICINES, YOU SHOULD ALWAYS TELL YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER TREATMENT YOU ARE TAKING particularly cardiac glycosides, cycline antibiotics, bisphosphonates, estramustine and iron salts.

PREGNANCY AND BREAST-FEEDING

If you are pregnant, do not take more than 1500 mg of calcium and 600 IU of vitamin D per day i.e. one tablet daily.

As a general rule, you should always seek the advice of your doctor or pharmacist before taking any medicine during pregnancy and breast-feeding.

LIST OF EXCIPIENTS WHICH NEED TO BE KNOWN FOR SAFE

USE IN CERTAIN PATIENTS: Aspartame, lactose.

HOW TO USE THIS MEDICINE?

DOSAGE

2 tablets daily.

METHOD AND ROUTE OF ADMINISTRATION

FOR USE IN ADULTS ONLY.

Oral route.

Tablet to be sucked followed by drinking a glass of water.

DURATION OF TREATMENT

Always follow the instructions on your doctor's prescription.

WHAT TO DO IF AN OVERDOSE IS TAKEN

If an overdose of this medicine is taken, the following symptoms may occur: nausea, vomiting, severe thirst, constipation.

If effects like these occur, tell your doctor immediately and he/she will take the action required. In the event of overdose over an extended period of time, calcifications may occur in the blood vessels or the tissues.

WHAT TO DO IF YOU FORGET TO TAKE ONE OR SEVERAL DOSES

If you forget to take a dose, do not take a double dose at your next dose.

UNDESIRABLE AND UNPLEASANT EFFECTS

As with all active products, this medicine can lead to annoying effects of varying severity in some people:

- constipation, diarrhoea,
- stomach pain, bloating,
- nausea,
- increased quantity of calcium in the blood or in the urine in some cases.

TELL YOUR DOCTOR OR PHARMACIST IF YOU NOTICE ANY UNWANTED AND ANNOYING EFFECTS WHICH ARE NOT MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT USE AFTER THE EXPIRY DATE STATED ON THE OUTER PACKAGING

DATE OF REVISION OF THE INFORMATION LEAFLET

June 2005