331.060

Zepita 3178
C1285ABF - City
of Buenos Aires
ARGENTINA

OVERDOSE:
Overdose is expressed in hypercalciuria and hypercalcemia showing the following symptoms: nausea, vomiting, polydipsia, polyuria, constipation.
Treatment: Discontinue any supplement of Calcium and Vitamin D and hydrate the patient. A chronic overdose of Vitamin D_3 may cause vascular and tissue calcifications as results of hypercalcemia.
In case of accidental intake or overdose attend nearest Hospital or contact toxicological centres.

STORAGE AND MAINTENANCE:
Keep at room temperature below 30ºC.

PRESENTATION:
Package containing 60 chewable tablets.

KEEP OUT OF REACH OF CHILDREN.

Do not administer after expiration date indicated in package

Medicament Authorized by the Ministry of Health of Argentina.
Register Nº 51.182

Manufactured by Laboratorios Temis Lostaló S.A., Zepita 3178 (C1285ABF) City of Buenos Aires, Argentine Republic.
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Last revised: September 2004

Ultracalcium D_3 400

Calcium / Vitamin D_3

chewable tablets

MANUFACTURED IN ARGENTINA
UNDER PRESCRIPTION ONLY

QUALI-QUANTITATIVE COMPOSITION:
Each chewable tablet contains:
Calcium (as Calcium carbonate) ..... 500,00 mg
Vitamin D_3 ..... 400,00 IU
Inactive ingredients: Instant Sorbitol, Orange essence, Colloidal silicon dioxide, Magnesium stearate, Croscarmellose sodium, Sunset yellow aluminium lake and Aspartame .....q.s.

THERAPEUTIC ACTION:
Calcium and Vitamin D_3 nutritional supplement (cholecalciferol).

INDICATIONS:
Correction of Vitamins and Calcium deficits in aged people.
Vitamin and Calcium additions associated to osteoporosis treatment, in patients with deficit or in risk of probable deficit of Calcium and Vitamin D.

DOSAGE AND ADMINISTRATION:
Doses shall be calculated on the basis of the daily requirements of elemental Calcium according to different ages and metabolic conditions, and also depending on the quantity of Calcium obtained from different foods.
As a guiding criterion the table below is suggested:

Teenagers and adults	**mg elementary Ca/day**
Under 24 years	1200 - 1500
Men:	
25 - 65 years	1000
Over 65 years	1500

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Women:	**mg elementary Ca/day**
25 - 50 years	1000
50 - 65 years (post menopausal):	
- Under estrogen therapy	1000
- No estrogen therapy	1500
Over 65 years	1500
Pregnant and lactating women	1200 – 1500

Cholecalciferol (Vitamin D_3) supplementing shall depend on the different metabolic conditions.
Generally 200 to 400 IU per day are necessary, but in some cases (especially in elderly patients), up to 800 IU/day should be added.
According to former paragraph ULTRACALCIUM D_3 400 daily dose shall oscillate between 1 to 2 daily tablets (equivalent to 500 to 1000 mg of elemental Calcium and 400 to 800 IU of Vitamin D_3) divided in two daily intakes.
Chew tablets in order to assure their bioavailability.

PHARMACOLOGICAL ACTION:
Calcium and Vitamin D contribution; medicine acting on Calcium balance (digestive and metabolic systems).
Vitamin D corrects the insufficiency of Vitamin D supply. Vitamin D increases Calcium absorption by the intestine and its fixation to the bone tissue. The Calcium supplement covers feeding Calcium requirements. Lacks of Calcium in aged people are estimated in 1500 mg/day of Calcium and 500 to 1000 IU/day of Vitamin D. Vitamin D and Calcium correct senile secondary hyperparathyroidism.

Pharmacokinetics
Calcium carbonate: Within the gastric environment, Calcium carbonate releases the Calcium ion in accordance with the pH. Calcium is essentially absorbed in the upper small intestine. Absorption rate through the gastrointestinal channel is about 30% of the dose taken. Calcium is eliminated through sweating and the digestive secretions. Calcium in urine depends on the glomerular filtration and the tubular reabsortion rate.
Vitamin D_3: Vitamin D_3 is absorbed in the intestine and transported by binding protein through bloodstream to liver, where the first hydroxylation takes place, and kidney, where the second hydroxylation takes place.
Non hydroxylated Vitamin D_3 is stocked in storing compartments such as adipose and muscular tissues. Plasma mean life is around one day. It is eliminated via the faeces and urine.

CONTRAINDICATIONS:
Hypercalcemia, hypercalciuria, calcium lithiasis. Long time immobilizations accompanied by hypercalciuria and/or hypercalcemia: Calcium-Vitamin treatment should not be administered until movement is recovered. Hypersensitivity to any of its components.

WARNINGS AND PRECAUTIONS:
In cases of long-term treatments, it is recommended to control calciuria and reduce or temporarily discontinue treatment in case calciuria is over 7,5 mmol/24 h (300 mg/24 hs). In case of concomitant treatment based on digitalics, biphosfonate, sodium fluoride, thiazidic diuretics, tetracycline: see drug interactions.

Vitamin D dose per intake unit (400 IU) and any other eventual prescription of Vitamin D should be considered. This product contains Vitamin D in itself, and a supplement of Vitamin D or Calcium should be administered under close medical follow-up, with a weekly control of calcemia and calciuria.
This medicine should be prescribed with caution to patients with sarcoidosis due to a probable increase in active Vitamin D metabolism. It should be cautiously administered in patients with renal impairment, with follow-up of phospho-calcium balance.

Use in pregnancy and lactation
Its administration during pregnancy or lactation should be avoided, unless otherwise recommended by physician.

INTERACTIONS
Drug interactions
Combinations that should be administered cautiously:
Digitalics: Calcium oral administration associated to Vitamin D increases toxicity of digitalics (risk of alterations in cardiac rhythm). Close clinical follow-up and, if applicable, electro-cardiographic and calcemia controls.
Diphosphonate, sodium fluoride: Wait at least two hours before taking Calcium (risk of decreased digestive absorption of diphosphonate and sodium fluoride).
Tiazidic diuretics: Calcemia monitoring is recommended (decrease of Calcium elimination).
Oral tetracycline: Wait at least three hours before Calcium intake. (Probable decrease of tetracycline absorption).
In case of supplementary administration of Vitamin D in high doses, a weekly control of calciuria and calcemia is required.
Phenytoin, barbiturates: Probable decrease of Vitamin D_3 effect due to the inhibition of its metabolism.
Glucocorticoids: Probable decrease of Vitamin D_3 effect.

Nutritional interactions:
Probable interaction with food (for example those containing oxalic acid, phosphates or phytates).