Just Chew It!

K-1000®

(Calcium + Vitamin D_3 + Vitamin K_2)

SUPPLEMENT FACTS:

Each chewable tablet contains:
Calcium Carbonate 1000mg (Elemental Calcium 400mg)
Vitamin D_3 600IU
Vitamin K_2 90mcg
(PharmEvo Specs.)

DESCRIPTION

K-1000 chewable tablet is a combination product containing Calcium, Vitamin D_3 (Cholecalciferol) and Vitamin K_2 (menaquinone-7) that helps strengthen bones and aids in the treatment/prevention of osteoporosis, osteomalacia, hypo-parathyroidism and other bone disorders or to overcome deficiencies of calcium and Vitamin D_3 in certain populations and disease states. It is also used to improve and maintain bone mineral density (BMD), bone health and strength.

PHARMACOLOGICAL AND THERAPEUTIC PROPERTIES

Calcium:

Calcium is required for vascular contraction and vasodilation, muscle function, nerve transmission, intracellular signaling and hormonal secretion, though less than 1% of total body calcium is needed to support these critical metabolic functions. Serum calcium is very tightly regulated and does not fluctuate with changes in dietary intakes; the body uses bone tissue as a reservoir for and source of calcium to maintain constant concentrations of calcium in blood, muscle, and intercellular fluids.

The remaining 99% of the body's calcium supply is stored in the bones and teeth where it supports their structure and function. Bone itself undergoes continuous remodeling with constant resorption and deposition of calcium into new bone. The balance between bone resorption and deposition changes with age. Bone formation exceeds resorption in periods of growth in children and adolescents, whereas in early and middle adulthood both processes are relatively equal. In aging adults, particularly among postmenopausal women, bone breakdown exceeds formation, resulting in bone loss that increases the risk of osteoporosis over time.

Vitamin D_3:

Vitamin D_3 promotes calcium absorption in the gut and maintains adequate serum calcium and phosphate concentrations to enable normal mineralization of bone and to prevent hypocalcemia tetany. It is also needed for bone growth and bone remodeling by osteoblasts and osteoclasts. Without sufficient Vitamin D_3, bones can become thin, brittle, or misshapen. Vitamin D_3 sufficiency prevents rickets in children and osteomalacia in adults. Together with calcium, Vitamin D_3 also helps protect older adults from osteoporosis.

Vitamin D_3 has other roles in the body, including modulation of cell growth, neuromuscular immune function and reduction of inflammation. Many genes encoding proteins that regulate cell proliferation, differentiation, and apoptosis are modulated in part by Vitamin D_3.

Vitamin K_2:

Vitamin K_2 is believed to help by preventing calcium from being deposited in your arteries by reducing arterial calcification. Vitamin K_2 plays a central role in the metabolism of calcium, the main mineral found in your bones and teeth. Vitamin K_2 activates the calcium-binding actions of two proteins, a matrix GLA protein and osteocalcin, which help to build and maintain bones.

SUPPLEMENT BENEFITS

K-1000 chewable tablets are used to prevent conditions related to calcium and Vitamin D_3 deficiency such as:
a) Osteoporosis
b) Osteomalacia
c) Hypoparathyroidism
d) Musculoskeletal pain

K-1000 chewable tablets are also used to overcome calcium and Vitamin D_3 deficiencies in certain populations and disease states such as:
a) Postmenopausal women
b) Bone recovery after fractures

K-1000 chewable tablets may also be used to prevent or treat bone-related disorders such as osteoporosis in people taking certain medication.

DOSAGE AND ADMINISTRATION

Take 1 tablet daily after meals or as directed by the physician.

Recommended Dietary Allowances (RDAs) for Calcium

Age	Male	Female	Pregnant	Lactation
0–6 months*	200 mg	200 mg	–	–
7–12 months*	260 mg	260 mg	–	–
1–3 years	700 mg	700 mg	–	–
4–8 years	1,000 mg	1,000 mg	–	–
9–13 years	1,300 mg	1,300 mg	–	–
14–18 years	1,300 mg	1,300 mg	1,300 mg	1,300 mg
19–50 years	1,000 mg	1,000 mg	1,000 mg	1,000 mg
51–70 years	1,000 mg	1,200 mg	–	–
71+ years	1,200 mg	1,200 mg	–	–

** NIH (National Institute of Health)*

Recommended Dietary Allowances (RDAs) for Vitamin D_3

Age	Male	Female	Pregnancy	Lactation
0–12 months*	400 IU (10 mcg)	400 IU (10 mcg)	–	–
1–13 years	600 IU (15 mcg)	600 IU (15 mcg)	–	–
14–18 years	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)
19–50 years	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)
51–70 years	600 IU (15 mcg)	600 IU (15 mcg)	–	–
>70 years	800 IU (20 mcg)	800 IU (20 mcg)	–	–

** NIH (National Institute of Health)*

Recommended Daily Allowances (RDAs) for Vitamin K_2

Age	Male	Female	Pregnancy	Lactation
Birth to 6 months	2.0 mcg	2.0 mcg	–	–
7–12 months	2.5 mcg	2.5 mcg	–	–
1–3 years	30 mcg	30 mcg	–	–
4–8 years	55 mcg	55 mcg	–	–
9–13 years	60 mcg	60 mcg	–	–
14–18 years	75 mcg	75 mcg	75 mcg	75 mcg
19+ years	120 mcg	90 mcg	90 mcg	90 mcg

**NIH (National institute of health)*

CONTRAINDICATIONS

K-1000 must not be used in patients with:

- Hypersensitivity to any of the active substances (Vitamin D_3 or its analogues, calcium or Vitamin K_2 or its analogues).

Due to calcium / cholecalciferol components, K-1000 tablets must not be used in:

- Hypercalcaemia and/or hypercalciuria
- Nephrolithiasis (Renal calculi)
- Hypervitaminosis D
- Severe renal impairment
- Metastatic calcification

WARNINGS AND PRECAUTIONS

This product should not be used in certain medical conditions, including:

- High calcium/Vitamin D_3 levels (hypercalcemia/hypervitaminosis D)
- Fat mal-absorption syndromes as the absorption of Vitamin K_2 is fat-dependent
- Known allergy to calcium, Vitamin D_3 or Vitamin K_2 containing products
- Cardiovascular disease (Heart/blood vessel disease). There is a risk of potential exacerbation of cardiac disorders and arteriosclerosis related to persistent hypercalcemic effects during therapeutic use of calcium/Vitamin D_3 products.
- Renal calculi (Kidney stones)
- Renal diseases (Kidney disease). Cholecalciferol should be used with caution in patients with impairment of renal function due to the potential exacerbation of hypercalcemic effects during therapeutic use. The effect on calcium and phosphate levels should also be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, Vitamin D_3 in the form of cholecalciferol is not metabolized normally and other forms of Vitamin D_3 should be used.
- Certain immune system disorder (Sarcoidosis). Cholecalciferol should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of Vitamin D_3 to its active form. These patients should be monitored with regard to the calcium content in serum and urine.
- Liver disease. In patients with liver impairment, Vitamin D_3 absorption may be markedly impaired; conversion to active metabolite calcifediol may be reduced significantly, with the requirement of high doses of cholecalciferol. Agents not requiring hepatic hydroxylation are preferred in this condition. It is not reasonable to use cholecalciferol in severe liver impairment.
- Certain bowel diseases (Crohn's disease, whipple's disease) that may cause fat mal-absorption and impair the absorption of Vitamin K_2
- Hyperlipidemia: Cholecalciferol may cause a potential exacerbation of LDL elevation
- Low levels of bile/biliary obstruction that may lead to fat mal-absorption and impair the absorption of Vitamin K_2
- Untreated phosphate imbalance. There is a risk of metastatic calcification; normalization of phosphate levels is indicated prior to therapy with cholecaciferol.

Do not exceed the recommended dose.
Pregnant or breast-feeding women shall consult health care professional before use. Please consult your pharmacist/doctor before taking this medicine.

ADVERSE REACTIONS

Common: Constipation or stomach upset may occur.
Uncommon: Hypercalcemia/hypercalciuria, Nausea/vomiting, loss of appetite, unusual weight loss, mental/mood changes, change in the amount of urine, bone/muscle pain, headache, increased thirst, increased urination, weakness, tiredness, fast/pounding heartbeat.
Rare: Serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

DRUG INTERACTIONS

Calcium can decrease the absorption of other drugs such as tetracycline antibiotics (e.g., doxycycline, minocycline), bisphosphonates (e.g., alendronate), estramustine, levothyroxine, and quinolone antibiotics (e.g., ciprofloxacin, levofloxacin). There should be a gap of at least 4 hours when taking these drugs with K-1000.

- Certain medications can decrease the absorption of Vitamin D_3 (bile acid sequestrants such as cholestyramine/colestipol, mineral oil, orlistat). There should be a gap of at least 4 hours when taking these drugs with K-1000.
- Patients co-treated with cardiac glycosides along with cholecalciferol may be susceptible to high calcium levels and should have ECG parameters and calcium levels monitored. It is recommended to reduce the dose or interrupt treatment if the calcium content in the urine exceeds 7.5 mmol/24 hours (300 mg/24 hours).
- Simultaneous administration of benzothiadiazine derivatives (thiazide diuretics increases the risk of hypercalcaemia because they decrease the calcium excretion in the urine. The calcium levels in plasma and urine should therefore be monitored for patients undergoing long-term treatment with calcium/Vitamin D_3 supplementation.
- Anti-convulsants e.g. phenytoin, phenobarbital, primidone, carbamazepine may diminish the effect of cholecalciferol due to hepatic enzyme induction. Rifampicin may reduce the effectiveness of cholecalciferol due to hepatic enzyme induction.
- Isoniazid may reduce the effectiveness of cholecalciferol due to inhibition of the metabolic activation of cholecalciferol.
- The cytotoxic agent actinomycin and imidazole antifungal agents interfere with Vitamin D_3 activity by inhibiting the conversion of 25-hydroxyVitamin D_3 to 1,25-dihydroxyVitamin D_3 by the kidney enzyme, 25-hydroxyVitamin D_3-1-hydroxylase.
  Concomitant use of glucocorticoids can decrease the effect of Vitamin D_3
- Vitamin K_2 supplementation may decrease the effectiveness of anticoagulant drugs such as warfarin. INR should be monitored closely and warfarin dose adjustment may be needed to optimize the effectiveness of warfarin, in patients taking concomitant Vitamin K_2 supplements.

USE IN SPECIAL POPULATIONS

Pregnancy

Use of a supplement containing calcium, cholecalciferol and Vitamin K_2 (menaquinone) is considered safe for pregnant mothers. No data is available regarding pregnancy outcomes after exposure to cholecalciferol (Vitamin D_3). Cholecalciferol should be used during pregnancy
Preferably only if the clinical condition of the woman requires treatment with cholecalciferol, at a dose necessary to overcome the deficiency. There are no adequate or well-controlled studies for the use of calcium in pregnant women. Fetal harm is not expected if the maternal calcium levels are maintained within the normal range. However, hypercalcemia during pregnancy may increase the risk for maternal and neonatal complications, such as stillbirth, preterm delivery, and neonatal hypocalcemia and hypoparathyroidism.
There are no adequate or well-controlled studies for the use of Vitamin K_2 analogues in pregnant women. Fetal harm is not expected with 90 mcg of Vitamin K_2. Nevertheless, Vitamin K_2 supplements should be given to pregnant women only if the potential benefit outweighs the potential risk to the fetus.

Lactation

Based on the information below, K-1000 in therapeutic doses of 1 tablet daily is considered safe during breast feeding. Cholecalciferol and its metabolites are excreted in breast milk. Caution is required with high doses to prevent the potential risk of hypercalcemia in infants. Serum calcium monitoring is advised. Potential benefits of treatment with cholecalciferol should be weighed against potential risks before prescribing it to breast feeding mothers.
Calcium is secreted in breast milk in significant amounts. However, infant harm is not expected if the maternal calcium levels are maintained within the normal range. Adverse effects in nursing infants have not been reported. Maternal medication with Vitamin K_2 and its analogues is compatible with breast feeding. No risk is expected with 90 mcg of menaquinone.

OVERDOSAGE

Calcium and Vitamin D_3

Acute or chronic overdose of calcium or Cholecalciferol can cause hypercalcemia, an increase in the serum and urinary concentrations of calcium. The symptoms of hypercalcemia are not very specific and consist of nausea, vomiting, diarrhea often in the early stages and later constipation, anorexia, fatigue, headache, muscle and joint pain, muscle weakness, polydipsia, polyuria, formation of renal calculi, nephrocalcinosis, kidney failure, and Calcification of soft tissues, changes in ECG measurements, arrhythmias and pancreatitis may develop. In rare and isolated cases there are reports that hypercalcemia is fatal.
The treatment with calcium and Vitamin D_3 must be discontinued. A low calcium or calcium-free diet can also be considered. Treatment with thiazide diuretics, lithium, vitamin A, Vitamin D3 and cardiac glycosides must also be discontinued. Treatment: rehydration, and, according to severity of hypercalcemia, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.
A normalization of hypercalcemia due to Vitamin D_3 intoxication lasts several weeks. Phosphate infusions should not be administered to lower hypercalcemia of hypervitaminosis D because of the dangers of metastatic calcification.

Vitamin K_2 (MenaQuinone)

There are no reports of Vitamin K_2 overdose available in literature. Toxicity is unlikely following oral exposure. Patient should be monitored in case of overdose and treated for any symptoms that may develop as a result of overdose.

PRESENTATION

K-1000: Pack of 30 chewable tablets.

ROUTE OF ADMINISTRATION

To be taken orally.

INSTRUCTIONS

Use as advised by the physician.
Keep out of the reach of children.
Protect from light, heat and moisture.
Store below 30°C.
For suspected adverse drug reaction, email us at reports@pharmevo.biz

Manufactured by:

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