اوپڈی۔کیل

OPDI-KAL™
Calcium, Vitamin D3, Vitamin K2

SUPPLEMENT FACTS
Each tablet contains:
Elemental Calcium.....500 mg
Vitamin D3 (Cholecalciferol).....600 IU
Vitamin K_2 (MK-7) 90mcg

DESCRIPTION
OPDI-KAL is a combination product containing calcium, Vitamin D3 (Cholecalciferol) and Vitamin K2 (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 in certain populations and disease states. It is also used to improve and maintain bone mineral density (BMD), bone health and strength.

PHARMACOLOGICAL PROPERTIES
Physiological and Therapeutic Properties
Calcium
Calcium is essential for the functional integrity of the nervous, muscular, and skeletal systems. The major fraction (99%) of calcium is in the skeletal structure primarily as hydroxyapatite, $Ca_{10}(PO_4)_6(OH)_2$; small amounts of calcium carbonate and amorphous calcium phosphates are also present. The calcium of bone is in a constant exchange with the calcium of plasma. Since the metabolic functions of calcium are essential for life, when there is a disturbance in the calcium balance because of dietary deficiency or other causes, the stores of calcium in bone may be depleted to fill the body's more acute needs. This may lead to bone disorders including osteoporosis. Calcium supplementation along with Vitamin D has been shown to reduce the risk of osteoporosis and osteomalacia.

Vitamin D3 (Cholecalciferol)
Cholecalciferol is produced within the skin under the influence of UV radiation including sunlight. In its biologically active form, cholecalciferol stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of cholecalciferol. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active cholecalciferol. Along with calcium supplementation, Vitamin D reduces the risk of osteoporosis and osteomalacia.

Vitamin K2
Vitamin K2 is required to activate osteocalcin, an important protein secreted by osteoblasts, the body's bone-building cells. When vitamin K2 is activated, osteocalcin can draw calcium into the bones where osteoblasts then incorporate it into the bone matrix. In addition, vitamin K2, when combined with vitamin D3, helps inhibit osteoclasts, the cells responsible for bone resorption. Vitamin K2 helps increase the amount of calcium deposited in bones and helps build bone density.

THERAPEUTIC USES
OPDI-KAL tablets are used to prevent and treat conditions related to calcium and vitamin D deficiency such as:
a) Osteoporosis
b) Osteomalacia
c) Hypoparathyroidism
d) Musculoskeletal pain
OPDI-KAL tablets are also used to overcome calcium and vitamin D deficiencies in certain populations and disease states such as:
a) Postmenopausal women
b) Bone recovery after fractures
OPDI-KAL tablets may also be used to prevent or treat bone-related disorders such as osteoporosis in people taking certain medication such as systemic corticosteroids (e.g. prednisone), phenytoin, phenobarbitone etc.

DOSAGE AND ADMINISTRATION
Take 1 tablet daily after meals or as directed by the physician
Dietary Reference Intakes (DRIs):
Recommended Dietary Allowances and Adequate Intake of Vitamin D, K & Calcium

Age Groups		Calcium (mg/dl)	Vitamin D (µg/dl)	Vitamin K (µg/dl)
Infants	0 – 6 mo	200*	10	2.0 mcg*
	6 -12 mo	260*	10	2.5 mcg*
Children	1 – 3 y	700	15	30 mcg*
	4 – 8 y	1,000	15	55 mcg*
Males	9–13 y	1,300	15	60 mcg*
	14–18 y	1,300	15	75 mcg*
	19–70 y	1,000	15	120 mcg*
	> 70 y	1,200	20	120 mcg*
Females	9–13 y	1,300	15	60 mcg*
	14–18 y	1,300	15	75 mcg*
	19–50 y	1,000	15	90 mcg*
	51–70 y	1,200	15	90 mcg*
	> 70 y	1,200	20	90 mcg*
Pregnancy & Lactation	14–18 y	1,300	15	75 mcg*
	19–50 y	1,000	15	90 mcg*

This table presents (RDAs) in bold type and (AIs) in ordinary type followed by an asterisk (*).
Food and Nutrition Board, Institute of Medicine, National Academies

CONTRAINDICATIONS
OPDI-KAL must not be used in patients with:
Hypersensitivity to any of the active substances (Vitamin D or its analogues, calcium or Vitamin K or its analogues)

Due to calcium / cholecalciferol components, OPDI-KAL 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 levels (hypercalcemia/hypervitaminosis D)

• Fat mal-absorption syndromes as the absorption of Vitamin K is fat-dependent

• Known allergy to Calcium, Vitamin D or Vitamin K 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 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 in the form of cholecalciferol is not metabolized normally and other forms of vitamin D 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 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 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

• 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

• Untreated phosphate imbalance. There is a risk of metastatic calcification; normalization of phosphate levels is indicated prior to therapy with cholecaciferol.

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 OPDI-KAL.
• Certain medications can decrease the absorption of vitamin D (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 OPDI-KAL.
• 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 (300mg/24 hours).
• Simultaneous administration of benzothiadiazine derivatives (thiazide diuretics increases the risk of hypercalcemia 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 supplementation.
• Anti-convulsants e.g. phenytoin, phenobarbital, primidone, carbamazapine 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 activity by inhibiting the conversion of 25-hydroxyvitamin D to 1,25-dihydroxyvitamin D by the kidney enzyme, 25-hydroxyvitamin D-1-hydroxylase.
• Concomitant use of glucocorticoids can decrease the effect of vitamin D

• Vitamin K 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 supplements

USE IN SPECIAL POPULATIONS

Pregnancy

Use of a supplement containing calcium, cholecalciferol and Vitamin K2 (menaquinone) is considered safe for pregnant mothers. No data is available regarding pregnancy outcomes after exposure to cholecalciferol (Vitamin D3). 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 analogues in pregnant women. Fetal harm is not expected with 90 mcg of Vitamin K2. Nevertheless, Vitamin K 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, OPDI-KAL 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 and its analogues is compatible with breast feeding. No risk is expected with 90 mcg of menaquinone.

OVERDOSAGE

Calcium and Vitamin D3

Acute or chronic overdose of Cholecalciferol or calcium can cause hypercalcaemia, an increase in the serum and urinary concentrations of calcium. The symptoms of hypercalcaemia are not very specific and consist of nausea, vomiting, diarrhoea 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 hypercalcaemia is fatal.

The treatment with calcium and Vitamin D must be discontinued. A low calcium or calcium-free diet can also be considered. Treatment with thiazide diuretics, lithium, vitamin A, vitamin D and cardiac glycosides must also be discontinued.

Treatment: rehydration, and, according to severity of hypercalcaemia, 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 hypercalcaemia due to vitamin D intoxication lasts several weeks. Phosphate infusions should not be administered to lower hypercalcaemia of hypervitaminosis D because of the dangers of metastatic calcification

Vitamin K2 (Menaquinone)

There are no reports of Vitamin K 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.

SHELF LIFE

Observe expiry date on the outer pack.

INSTRUCTIONS

Use as advised by the physician.
Do not store above 30 °C.
Protect from heat, light & moisture.
Keep all medicines out of reach of children.

ہدایات:

۳۰ ڈگری سینٹی گریڈ سے زیادہ درجۂ حرارت پر نہ رکھیں۔
گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

PRESENTATION:

OPDI-KAL (Calcium 500 mg + Vitamin D3 600 IU + Vitmain K_2 90 mcg) is supplied in a jar of 30 tablets.

MANUFACTURED FOR:

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