



07-03-2022

1st Copy

210mm

intig-D[®] Tablets / Suspension

(Ossein Mineral Complex + Vitamin D)

QUALITATIVE AND QUANTITATIVE COMPOSITION

intig-D[®] Tablets

Each film coated tablet contains:

Vitamin D MS.....	400 I.U.
Ossein Mineral Complex MS.....	830mg
corresponding to:	
Calcium.....	177.6mg*
Phosphorus.....	82.2mg*
Residual Mineral Salts.....	24.9mg
Collagen.....	224.0mg
Other Proteins.....	66.4mg
Trace Elements.....	F, Mg, Fe, Zn, Cu, Ni

*corresponding to approx. 440mg hydroxyapatite

intig-D[®] Suspension

Each 5ml contains:

Vitamin D MS.....	400 I.U.
Ossein Mineral Complex MS.....	250mg
corresponding to:	
Calcium.....	53.5mg*
Phosphorus.....	24.8mg*
Residual Mineral Salts.....	7.5mg
Collagen.....	67.5mg
Other Proteins.....	20mg
Trace Elements.....	F, Mg, Fe, Zn, Cu & Ni

*corresponding to approx. 132mg hydroxyapatite

PHARMACEUTICAL FORM

Tablet and Suspension.

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS:

Supplemental mineral deficiency, especially calcium and phosphorus.

- Increased mineral requirements during pregnancy and lactation.
- Osteoporosis/osteomalacia.
- Osteoarthritis.
- Rickets.
- Bone pain and bone fragility.
- Stiffness in the joints.
- Fatigue.
- Hypocalcaemia.
- Prophylaxis against dental caries.
- As adjuvant in fractures with delayed callus formation.

POSLOGY AND METHOD OF ADMINISTRATION:

Tablet:

1 to 2 tablets daily before meal with water / juice or as prescribed by the physician.

Suspension:

Children: 1 to 2 teaspoonfuls (5 to 10ml) daily before meal or as prescribed by the physician.

Adults: 1 to 2 tablespoonfuls (15 to 30ml) daily before meal or as prescribed by the physician.

CONTRAINDICATIONS:

Contraindicated in patients with:

- History of hypersensitivity to drug.
- Hypercalcaemia and hypercalciuria.
- Severe renal failure.
- Urolithiasis.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

- Precaution should be taken in patients with known hypersensitivity to Vitamin D or any of its derivatives.
- Precaution should be taken in patients who are having excess intake of Vitamin D that may lead to hypercalcaemia for excess bone loss.
- Use carefully in patient with cardiac disease and atherosclerosis.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

- Concurrent administration of phenobarbital, phenytoin may increase cholecalciferol metabolism.
- Concurrent administration of thiazides may risk of hypercalcaemia.
- Concurrent administration of cholestyramine or colestipol hydrochloride may result in decreased intestinal absorption of vitamin D analogs.
- Concurrent administration of orlistat may result in decreased GI absorption of fat-soluble vitamins such as vitamin D analogs. At least 2 hours should elapse between (before or after) any orlistat dose and vitamin D analog administration.
- Concurrent use of vitamin D analogs and cardiac glycosides may result in cardiac arrhythmias.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy: There are no adequate or well controlled studies in pregnant women.

However, the mother and fetus from untreated maternal hypoparathyroidism and hypophosphatemia are considered greater than the risks due to vitamin D therapy.

Lactation: Vitamin D is distributed into breast milk. Use of vitamin D is usually considered compatible with breast feeding. But large dose should not be administered to the nursing women. The infant should be closely monitored for hypercalcaemia or clinical manifestations of vitamin D toxicity if the mother is receiving pharmacological doses of vitamin D.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not known

UNDESIRABLE EFFECTS:

Chronic administration of excessive doses of vitamin D analogs may lead to hypervitaminosis D and hypercalcaemia.

OVERDOSE:

Both the drug and calcium supplements should be withdrawn, maintenance of a low-calcium diet, administration of oral or IV fluids and if needed, corticosteroids or other drugs, particularly calcic diuretics (e.g., furosemide and ethacrynic acid) to decrease serum calcium concentrations. Haemodialysis or peritoneal dialysis against a calcium-free dialysate may also be used. If ingestion is recent, gastric lavage or emesis may prevent further absorption. If the drug has passed through the stomach, administration of mineral oil may promote fecal elimination.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES:

Contains vitamin D and ossein mineral components of bone tissue in the physiological proportions, including calcium and phosphate, trace elements, fluoride and other ions, proteins and glycosaminoglycans. It is given orally to patients requiring both calcium and phosphorus supplementation.

The anti-osteoporotic activity is based on a dual effect: An anabolic effect on osteoblast and an anticatabolic effect on osteoclasts. These 2 different types of action are physiologically complementary: Balance bone resorption and bone formation or bone remodeling.

120mm



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PHARMACOKINETIC PROPERTIES:

Vitamin D substance are well absorbed from the gastrointestinal tract, absorption may be decreased in patients with decreased fat absorption. Certain vitamin D substances may be distributed into breast milk. Vitamin D may accumulate in fat tissue and muscle for a long time. Cholecalciferol has a slow-acting effect but a long duration of action.

SHELF LIFE

See expiry on the pack.

AVAILABILITY

intig-D film coated tablets in a pack of 30's

intig-D suspension in a pack of 60ml

intig-D suspension in a pack of 120ml

INSTRUCTIONS

Dosage: As advised by the physician.

To be sold on the prescription of registered medical practitioner.

Keep out of reach of children.

Avoid exposure to heat, light, humidity and freezing.

Store between 15 to 30°C.

Improper storage may deteriorate the medicine.

انٹگ-ڈی ٹیبلٹ / سسپینشن
(اوہٹین مہزل کپلیکس + وٹامن ڈی)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو گرمی، روشنی، نمی اور مہند ہونے سے محفوظ رکھیں ۱۵ سے ۳۰

ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmagk.com
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