Indomac انڈومیک

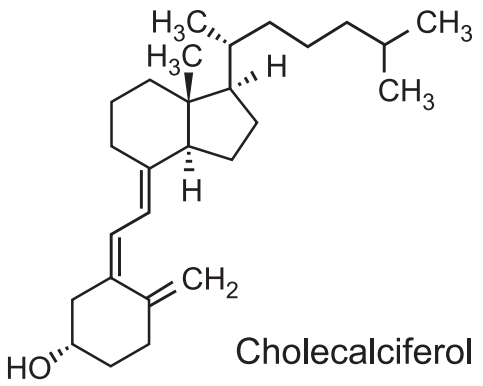
(Cholecalciferol)

(کول کیلسی فِرول)

Vitamin D_3 Injection 5mg/ml
For Oral and IM administration

COMPOSITION
Each 1ml ampoule contains:
Cholecalciferol (BP)…….5mg.
Finished Product Specs: Innovator's Specifications.

DESCRIPTION
indoMac (Cholecalciferol) increase the capacity of intestine to absorb calcium and phosphates. It also supports bones in the process of mineralization.



Cholecalciferol

CLINICAL PHARMACOLOGY
Mechanism of Action
Calcitriol, which is the metabolite of cholecalciferol, exerts its effect by binding to the vitamin D receptors (VDRs) which are widely distributed through many body tissues. Cholecalciferol also has anti-osteoporotic, immunomodulatory, anticarcinogenic, antipsoriatic, antioxidant & mood-modulatory activities and along with parathyroid hormone & calcitonin it regulates serum calcium concentration.

Pharmacokinetics
Absorption:
Cholecalciferol is well absorbed in the small intestine.

Distribution:
Its essential storage sites are adipose tissue, muscles, but also blood. 25-hydroxyvitamin D bound to its carrier protein is the major circulating reserve form of vitamin D.

Metabolism:
After absorption, Cholecalciferol binds to a specific carrier protein and is transported to the liver where it is converted into 25-hydroxyvitamin D. The latter in turn binds to the same carrier protein and is transported to the kidneys where it is transformed into its active form, 1,25-dihydroxyvitamin D.

Elimination: Cholecalciferol and its metabolites are eliminated via the fecal route in untransformed form or in water-soluble form (calcitroic acid, glucuronide derivatives).

INDICATIONS AND USAGE
indoMac (Cholecalciferol) Vitamin D_3 Injection 5mg/ml is indicated in prophylaxis and / or treatment of vitamin D deficiency.

DOSAGE AND ADMINISTRATION
indoMac (Cholecalciferol) Vitamin D_3 Injection 5mg/ml can be administered through IM route or the ampoule can also be administered orally. The dosages are as follows:

Infants receiving milk fortified with Vitamin D:
1/2 ampoule (i.e., 100,000 IU) every 6 months.

Breastfed infants or infants not receiving vitamin D-enriched milk and in young children up to 5 years of age:
1 ampoule (i.e., 200,000 IU) every 6 months.

Adolescents:
1 ampoule (200,000 IU) every 6 months during the winter period.

Pregnant women:
1/2 ampoule (i.e., 100,000 IU) in the 6^{th} or 7^{th} month of pregnancy, repeated once after one month, when the last trimester of pregnancy begins during the winter period or in the event of no sun exposure.

Elderly:
1/2 ampoule (i.e., 100,000 IU) every 3 months.

In Children or adults with a digestive pathology:
1/2 to 1 ampoule (i.e., 100,000 to 200,000 IU) every 3 months.

In Children or adults on anticonvulsant therapy:
1/2 to 1 ampoule (i.e., 100,000 to 200,000 IU) every 3 months.

In children or adults in other special conditions other than those described above:
1 ampoule (i.e., 200,000 IU) every 6 months.

Treatment of Vitamin D_3 deficiency (rickets, osteomalacia, neonatal hypocalcemia):
1 ampoule (200,000 IU) possibly repeated once after 1 to 6 months.

CONTRAINDICATIONS
indoMac (Cholecalciferol) Injection 5mg/ml is contraindicated in patients with hypersensitivity to the any of the substance used in indoMac. It is also contraindicated in case of hypercalcemia, hypercalciuria, calcium lithiasis.

SIDE EFFECTS
Common (may affect up to 1 in 10 people):
On IM administration, the occurrence of reactions at the injection site, such as pain, itching, infection, granuloma, panniculitis, redness, nodule or urticaria is possible.

Very rare (may affect up to 1 in 10,000 people):
Hypersensitivity reaction, hypercalcemia, hypercalciuria, kidney stones can be observed in particular in the event of overdose.

WARNINGS AND PRECAUTIONS

- Consider the total vitamin D doses in case of combination of several treatments containing this vitamin to avoid overdose.
- Monitor urinary and serum calcium and stop the intake of vitamin D if urinary calcium levels exceed 105mg/ml (2.62mmol/l) or if urinary calcium exceeds 4mg/kg/day in adults or 4-6mg/kg/day in children.
- In case of high calcium intake, regular control of calciuria is essential.

DRUG INTERACTIONS

Enzyme-inducing anticonvulsants:
Decrease in vitamin D concentrations more marked than in the absence of an inducer.
Rifampicin:
Decrease in vitamin D concentrations more marked than without treatment with rifampicin.
Orlistat:
Decreased absorption of vitamin D.

OVERDOSAGE

Signs resulting from the overdosage of vitamin D or its metabolites;

Clinical Signs of Overdosage:
Hypercalcemia, headache, asthenia, anorexia, weight loss, depression, stunted growth, nausea, vomiting, constipation, polyuria, polydipsia, dehydration, high blood pressure, calcium lithiasis, tissue calcifications in particular renal and vascular, kidney failure, heart rhythm disturbance, even coma.

Biological signs of Overdosage:
Hypercalciuria, hypercalcemia, hyperphosphatemia, low concentration of parathyroid hormone, high concentration of 25-hydroxyvitamin D.

Treatment of Overdosage:
Stop the administration of vitamin D, reduce calcium intake, increase diuresis, drink plenty of fluids.

STORAGE

Store below 30ºC.
Protect from heat & light.

PRESENTATION

indoMac (Cholecalciferol) Injection 5mg/ml is available as pack of 1's.

To be sold on prescription of a registered medical practitioner only.

Keep all medicines out of the reach of children

Manufactured by :
Indus Pharma (Pvt.) Ltd.
65/27, Korangi Industrial Area,
Karachi-74900, Pakistan.

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