

PACKAGE INSERT

Cholecalciferol Oral Suspension 800 IU / 5 ml

JusDee®
800 Suspension

जस्टडी 800

Composition

Each 5 ml contains:

Cholecalciferol IP 800 IU

Colour: Quinoline Yellow

Appropriate Overages of vitamin added to compensate loss on storage.

Clinical Pharmacology

Cholecalciferol (Vitamin D₃) is the naturally occurring form of Vitamin D. Vitamin D₃ supplementation is important for the maintenance of strong healthy bones and teeth. Vitamin D₃ is utilized by many organs, cells and systems in the body. It plays an intrinsic role in Calcium metabolism, the immune and nervous systems, bone, heart and kidney health. Vitamin D is generally produced by the body through sunlight and is necessary for the absorption of Calcium. Individuals who are not exposed to sufficient sunlight or are unable to produce Vitamin D require additional Vitamin D supplementation.

Vitamin D substances are well absorbed from the gastrointestinal tract. The presence of bile is essential for adequate intestinal absorption; absorption may be decreased in patients with decreased fat absorption. Because Vitamin D is fat soluble, it is incorporated into chylomicrons and absorbed via the lymphatic system; approximately 80% of ingested Vitamin D appears to be absorbed systemically through this mechanism, principally in the small intestine. After absorption, Cholecalciferol enters the blood via chylomicrons of lymph and then associate mainly with a specific alpha-globulin (Vitamin D-binding protein). Cholecalciferol are stored in fat and muscles for prolonged periods. In the liver, Cholecalciferol is converted in the mitochondria to their 25-Hydroxy derivatives by the enzyme Vitamin D 25-hydroxylase. Further metabolism also occurs in the kidneys, including the formation of the 1,24,25-trihydroxy derivatives.

Vitamin D compounds and their metabolites are excreted mainly in the bile and faeces with only small amounts appearing in urine; there is some enterohepatic recycling but it is considered to have a negligible contribution to Vitamin D status. Certain Vitamin D substances may be distributed into breast milk.

Indications

JusDee 800 Suspension is used to prevent rickets, infantile tetany, conditions of inadequate exposure to sunlight and in cases where Vitamin D cannot be adequately absorbed.

Contraindications

Hypersensitivity to active substances or to excipients, hypercalcaemia, hypercalciuria, severe renal insufficiency, kidney stones, calcium lithiasis, calcification of tissues, hypervitaminosis D.

Warning & Precautions

To be used with caution and care in patients with impaired renal function or disease associated with elevated Vitamin D concentrations such as sarcoidosis.

Adverse Effects

Cholecalciferol (Vitamin D) at normal doses usually has no side effects. Some side effects of taking too much Vitamin D include weakness, fatigue, sleepiness, headache, loss of appetite, dry mouth, metallic taste, nausea, vomiting, and others. Some infants and patients with sarcoidosis or hypoparathyroidism may have increased sensitivity to Vitamin D.

Drug Interactions

Colestyramine, corticosteroids and mineral oils interfere with and reduce Vitamin D absorption, while Phenytoin and Barbiturates favour its inactivation.

Overdose

Overdose is extremely unlikely if the dosage recommendations are followed. Some side effects of taking too much Vitamin D include weakness, fatigue, sleepiness, headache, loss of appetite, dry mouth, metallic taste, nausea, vomiting, and others. Some infants and patients with sarcoidosis or hypoparathyroidism may have increased sensitivity to Vitamin D. In case of accidental overdose, symptomatic treatment

Usage In Pregnancy and Lactation

Not applicable

Dosage

For the use of Children : 5 ml once daily (or) as directed by the Physician. The required dosage is to be administered using specially marked 10 ml measuring cup provided in the pack SHAKE WELL BEFORE USE.

FOR THERAPEUTIC USE**Incompatibilities**

None

Shelf Life

18 months

Storage

Do not store above 30°C. Protect from light. KEEP OUT OF REACH OF CHILDREN.

Presentation

50 ml amber coloured bottles packed in outer carton with a 10 ml measuring cup.



Manufactured in India by:
STEDMAN PHARMACEUTICALS PVT. LTD.
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