DEFORT-3
Instructions
for medical use of the drug

Trade name: Defort-3.
INN: Cholecalciferol.
Chemical name:
Cholecalciferol: 24,25-Dihydroxyvitamin D 3 (24,25(O h)2d3).
Dosage form: Solution for injection and for oral administration.
Composition: *1 ml of solution contains:*
Active substances:
Cholecalciferol……. USP 300 000 IU /ml;
Excipients:
Diglycerides, cardamom oil.
Pharmacotherapeutic group: Regulating calcium-phosphorus metabolism. Vitamin D and its derivatives. Cholecalciferol. Vitamins and vitamin-like products.
ATX code: A11CC05.
Pharmacological properties:
Pharmacodynamics:
A drug that regulates the metabolism of calcium and phosphorus. Enhances the absorption of calcium in the intestine and the reabsorption of phosphorus in the renal tubules. Promotes the formation of the bone skeleton and teeth in children, preserving bone structure.
Vitamin D 3 is necessary for the normal functioning of the parathyroid glands, and is also involved in the functioning of the immune system, influencing the production of lymphokines .
Participates in the process of ATP synthesis.
As a hormone it acts on the cells of the intestines, kidneys and muscles. In the cells of the intestinal mucosa, vitamin D stimulates the synthesis of the carrier protein necessary for Ca transport. The action of parathyroid hormone, manifested by increased calcium absorption, is carried out entirely through its stimulating effect on the production of 1,25-(O)2- D 3 by the kidneys. Phosphorus absorption is also stimulated by vitamin D. The increase in tissue mineralization processes during treatment with vitamin D appears to be a consequence of an increase in the content of Ca and phosphorus in the plasma. Calcitriol is able to increase Ca reabsorption, but to a moderate extent, since 99% of Ca is reabsorbed even in the absence of vitamin D. In muscle tissue, with vitamin D deficiency, calcium uptake by the sarcoplasmic reticulum is reduced, which is manifested by muscle weakness. The process of hormone formation is regulated by the body's need for Ca and phosphorus and is mediated by parathyroid hormone and the phosphorus content in the blood.
*Pharmacokinetics***:**
In the blood, most of it is bound to gamma globulins and albumins. Vitamin D is stored mainly in adipose tissue. The main processes of vitamin D biotransformation occur in the skin, liver and kidneys. In the skin, under the influence of ultraviolet irradiation, vitamin D 3 is formed from precursors. In the liver, vitamin D undergoes hydroxylation and is then converted into 25-hydroxycholecalciferol (25-OH- D 3). The latter in the kidneys, with the participation of parathyroid hormone, is converted into the most active metabolite of vitamin D-calcitriol, or 1,25-dihydroxycholecalciferol (1,25(OH)2- D3), which is considered a potent renal hormone with a steroid structure. l ,25-(OH)2- D3 plays an important role in regulating the metabolism of Ca, P and divalent trace elements (Cd, Ni, Zn, Hg, Be, Sr). The half-life of vitamin D from the body is about 19 days. It is excreted through bile excretion, initially into the intestine (15-30% of the administered dose during the day), where it undergoes enterohepatic circulation (reabsorption). The remaining part is excreted with the contents of the intestine. The rate of disappearance of the original vitamin from blood plasma is 19-25 hours, but when accumulated in tissues, its residence time in the body can be up to 6 months.
Toxicology:
Symptoms of chronic vitamin D intoxication (when taken for several weeks or months for adults in doses of 20-60 thousand IU / day, children - 2-4 thousand IU / day): calcification of soft tissues, kidneys, lungs, blood vessels, arterial hypertension, renal and chronic heart failure (these effects most often occur when hyperphosphatemia is added to hypercalcemia), growth impairment in children (long-term use at a dose of 1.8 thousand IU/day).
Indications for use:
- Hypo- and vitamin D deficiency (prevention and treatment);

- Rahit, spasmophili;
- O Steoporosis in postmenopausal women (as part of complex therapy), osteomalacia;
- Type 2 diabetes;
- Hypertension and disruption of the cardiovascular system;
- Multiple sclerosis and Parkinson's disease ;
- Depression and frequent headaches;
- Breast and ovarian cancer in women;
- Nephrogenic osteopathy;
- Inadequate and unbalanced nutrition (including parenteral, vegetarian diet);
- Alcoholism;
- Liver failure, cirrhosis;
- Pregnancy (especially with nicotine and drug addiction, multiple pregnancy), lactation period;
- Malabsorption syndrome ;
- Hypocalcemia , hypophosphatemia (including familial);
- With insufficient insolation;
- Taking barbiturates, cholestyramine, colestipol, mineral oils, anticonvulsants (including phenytoin and primidone);
- Hypoparathyroidism: postoperative, idiopathic;
- Tetany (postoperative and idiopathic), pseudohypoparathyroidism.

Contraindications:

- in the presence of hypersensitivity reactions to the substance;
- vitamin D3 hypervitaminosis;
- patients with hypercalciuria, hypercalcemia, calcium nephrourolithiasis;
- in large dosages in bedridden patients;
- with hyperphosphatemia, renal osteodystrophy;
- patients with sarcoidosis;
- with an active form of pulmonary tuberculosis.

Carefully:

The drug should be prescribed with caution for atherosclerosis, heart failure, renal failure, pulmonary tuberculosis (active form), hyperphosphatemia, phosphate nephrolithiasis, organic heart damage, acute and chronic liver and kidney diseases, gastrointestinal diseases (including gastric ulcer and duodenum), during pregnancy and lactation, with hypothyroidism.

Use for liver dysfunction*:*

The drug should be prescribed with caution for acute and chronic liver diseases.

Use for renal impairment:

The drug should be prescribed with caution in case of renal failure, phosphate nephrolithiasis, acute and chronic kidney diseases.

Side effects:

From the side of electrolyte metabolism: hyperphosphatemia, hypercalcemia, hypercalciuria.

From the digestive system: anorexia, constipation.

From the urinary system: polyuria, renal failure.

From the side of the central nervous system: headache.

From the musculoskeletal system: myalgia, arthralgia.

From the cardiovascular system: increased blood pressure, arrhythmias.

Other: allergic reactions.

Directions for use and dosage:

The drug is used both intramuscularly (IM) and orally.

The drug is administered intramuscularly in a clinical/hospital setting under the supervision of a qualified healthcare professional to confirm the safety of intramuscular cholecalciferol therapy.

Children and teenagers (2-18 years):

Prevention: 1 ampoule (300,000 IU vitamin D3) once a year.

Treatment: 1 ampoule (300,000 IU vitamin D3) every 3 months.

Adults and seniors:

Prevention: 1 ampoule (300,000 IU vitamin D3) once a year. In patients at high risk of deficiency, the dose may need to be increased to 1 ampoule (300,000 IU vitamin D3) every 6 months.

Treatment: 1 ampoule (300,000 IU vitamin D3) every 6 weeks. Adequate calcium intake is essential for treatment to be effective.

Overdose:

Symptoms of hypervitaminosis D: early (due to hypercalcemia) - constipation or diarrhea, dry oral mucosa, headache, pollakiuria, nocturia, polyuria , anorexia, metallic taste in the mouth, nausea, vomiting, unusual fatigue, general weakness, hypercalcemia, hypercalciuria; late - bone pain, cloudiness of urine (appearance of hyaline casts in the urine, proteinuria, leukocyturia), increased blood pressure, skin itching, photosensitive eyes, conjunctival hyperemia, arrhythmia, drowsiness, myalgia, nausea, vomiting, pancreatitis, gastralgia, weight loss, rarely - psychosis (changes in mentality and mood).

Symptoms of chronic overdose of vitamin D (when taken for several weeks or months for adults in doses of 20-60 thousand IU /, for children - 2-4 thousand IU /): calcification of soft tissues, kidneys, lungs, blood vessels, arterial hypertension, renal and chronic heart failure (these effects most often occur when combined with hypercalcemia, hyperphosphatemia), growth impairment in children (long-term use).

Treatment: discontinuation of the drug, diet low in calcium, consumption of large amounts of fluid, administration of corticosteroids, α-tocopherol, ascorbic acid, retinol, thiamine, in severe cases - intravenous administration of large quantities of 0.9% sodium chloride solution, furosemide, electrolytes, hemodialysis. There is no specific antidote. To avoid overdose, in some cases it is recommended to determine the concentration of calcium in the blood.

Drug interactions:

With simultaneous intake of vitamin D3 s Thiazide diuretics increase the risk of developing hypercalcemia.

When used simultaneously with phenytoin (increasing the rate of biotransformation), cholestyramine, ECS, calcitonin, derivatives of etidronic and pamidronic acids, plicamycin, gallium nitrate, the effectiveness of the drug containing vitamin D3 is reduced.

Retinol, when used simultaneously with vitamin D3, reduces the toxicity of the latter.

Barbiturates, when used simultaneously with vitamin D3, increase the rate of biotransformation colecalciferol.

Vitamin DZ, when used simultaneously, increases the toxicity of cardiac glycosides.

Long-term therapy with the drug, against the background of simultaneous use of antacids containing aluminum and magnesium, increases their concentration in the blood and the risk of intoxication (especially in the presence of chronic renal failure).

Cholestyramine, colestipol and mineral oils reduce the absorption of colecalciferol in the gastrointestinal tract, which requires increasing its dose when used simultaneously with the above drugs.

Cholecalciferol increases the absorption of phosphorus-containing drugs and the risk of hyperphosphatemia .

When using the drug simultaneously with sodium fluoride, the interval between doses should be at least 2 hours, with oral forms of tetracyclines - at least 3 hours. Simultaneous use with other analogues of vitamin D 3 increases the risk of developing hypervitaminosis.

Pregnancy and breastfeeding:

Hypercalcemia during pregnancy can cause defects in the physical and mental development of the fetus.

Vitamin D 3 and its metabolites pass into breast milk.

During pregnancy and lactation, the daily dose of colecalciferol should not exceed 600 IU.

Special instructions:

When used prophylactically, overdose should be avoided, especially in children (do not prescribe more than 10-15 mg per year).

When using doses above 1000 IU, as well as when taking the drug continuously for several months, periodic determination of the concentration of calcium and phosphorus in the blood serum is recommended to exclude chronic hypervitaminosis D 3 and hyperphosphatemia.

In order to prevent the development of hyperphosphatemia in patients with bone lesions of renal origin, the drug can be prescribed together with phosphate binders.

Release form and packaging:

Solution for injection and for oral administration, 1 ml in a transparent glass ampoule.

1 ampoule along with instructions for use are placed in a cardboard box.

Storage conditions:

Store in a dry place, protected from light, at a temperature not exceeding 25 °C.

Keep out of the reach of children.

Do not use after the expiration date stated on the package.

Conditions for dispensing from pharmacies:

By doctor's prescription

Made for:
MAXX PHARM LTD
London, Great Britain