

Detrimed 10 ml and 15 ml

Pharmaceutical form: Oral drops

Composition: One milliliter of solution (30 drops) contains 15 000 IU of cholecalciferol.

Excipients: macrogol tricetylricinoleate, sucrose 250 mg, disodium phosphate dodecahydrate, citric acid monohydrate, banana flavor, benzyl alcohol 15 mg, purified water.

Pharmacological group: Vitamins and vitamin-like drugs.

Pharmacodynamics:

The active form of Vitamin D is stimulating absorption of calcium in the intestines, including of calcium into osteoid and elimination of calcium from bone tissue. In the small intestines it stimulates immediate and delayed calcium uptake. Also under the influence of Vitamin D passive and active transport of phosphorus is increased. In the kidneys, it inhibits discharge of calcium and phosphorus by stimulating of calcium reabsorption. Production of parathyroid hormone (PTH) by parathyroid glands directly inhibited by biological active form of vitamin D. Also secretion of PTH inhibited due to the increase blockading of calcium in the small intestines by influence of biological active form of vitamin D.

Pharmacokinetics:

Vitamin D well absorbs from gastro-intestinal tract in the presence of bile, that's why the prescription of vitamin D with the meal can contribute to its complete absorption. In the liver vitamin D hydroxylates to 25-hydroxycalciferol and incurs further hydroxylation in kidneys to active metabolite 1,25 dihydroxycholecalciferol (calciferol). Metabolites circulating in the blood contact to specific α – globin. Vitamin D and his metabolites are excreting with bile and feces.

Indications:

- for the prevention of rickets in children (disturbance of bones mineralization in children, often due to deficiency of vitamin D₃) and osteomalacia of adults (insufficient mineralization of bones in adults, arising mainly from deficiency of vitamin D₃);
- for the prevention of rickets in premature infants;
- for the prevention of an established risk of deficiency of vitamin D₃ in children and adults;
- for the prevention of deficiency of vitamin D₃ in children and adults with digestive disorder diagnosed by doctor;
- for the prevention of rickets in children and osteomalacia of adults;
- as a maintenance therapy of osteoporosis of adults.

- for treatment of disturbance of parathyroid glands of adultes.

Contraindications:

- if you have an allergy from vitamin D₃ and any other drug ingredient;
- if you have an increased level blood calcium content (hypercalcemia);
- if you have an increased urinary calcium content (hypercalciuria);
- if you have pseudohypoparathyreose (disturbance of metabolism of parathyroid hormone);
- if you have kidney failure and or urolithiasis, or you have a tendency to form stones in the kidneys;
- if you have increased level of vitamin D₃ in blood (hypervitaminosis of D).

Dosage and administration:

Prevention of rickets and osteomalacia

Children and adultes: 1 drop daily (equivalent to 500 IU of vitamin D₃)

Premature infants: 2 drops daily (equivalent to 1000 IU of vitamin D₃) to adjusted to post-conceptual age of 40 weeks. After that the prevention dose of vitamin D₃ must be reduced.

The dosage regimen is determined by attending doctor individually.

Prevention of deficit of vitamin D₃ in children and adultes from risk group of 1 daily (equivalent to 500 IU of vitamin D₃).

Prevention of deficit of vitamin D₃ in children and adultes with syndrome of malabsorption 6-10 drops daily (equivalent to 3000 IU – 5000 IU of vitamin D₃).

Treatment of rickets

In newborns, children of the first year of life and young children (from 0 to 5 years):

2-4 drops daily (equivalent to 1000 IU - 2000 IU of vitamin D₃).

In children over aged 5 years and adolescents:

4-10 drops daily (equivalent to 2000 IU - 5000 IU of vitamin D₃).

Treatment of osteomalacia

Adultes: 2-10 drops daily (equivalent to 1000 IU - 5000 IU of vitamin D₃).

Maintenance Therapy for Osteoporosis

2 drops daily (equivalent to 1000 IU of vitamin D₃).

For the treatment of parathyroid gland disorders:

Adultes:

Recommended dose range is 10 000 to 200 000 IU of vitamin D₃ daily depending on serum calcium levels.

In most patients, the daily dose of vitamin D₃ is up to 10 000 IU (up to 20 000 IU). At the beginning of therapy, serum calcium levels should be determined every 4-6 weeks, and every 3-6 months thereafter.

The dose must be adjusted based on the level of calcium in the serum.

Administration

In newborns, children of the first year of life and young children (from 0 to 2 years):

Before taking it is recommended to dilute the required amount of the drug Detrimed in a teaspoon of milk or water. When adding drops into a bottle or plate with food, make sure that all food with Detrimed is taken, otherwise it is impossible to guarantee the intake of the entire dose. Drops should be added only cooked and sufficiently cooled food.

In children over 2 years, adolescents and adults:

Detrimed is taken with a small amount of liquid.

Side effects:

Immune System Disorders - Decreased appetite, weight loss, excessive thirst

Psychiatric disorders - Low mood psychotic disorders, decreased libido

Nervous System Disorders - Headache, drowsiness

Eye disorders - Hypersensitivity to light, inflammation of the eyes

Cardiac Disorders - Heart Rhythm Disorders

Vascular disorders - Increased blood pressure

Blood and Lymphatic System Disorders - Elevated blood cholesterol levels

Liver and Biliary Disorders - Elevated liver function tests

Gastrointestinal Disorders - Inflammation of the pancreas. Dry mouth, nausea, vomiting, constipation, flatulence, abdominal pain, or diarrhea.

Skin and subcutaneous tissue disorders - Increased calcium levels in the blood, urine and tissues. Skin rashes, urticaria, itching, increased sweating.

Musculoskeletal and connective tissue disorders - Muscle and joint pain, muscle weakness.

Renal and urinary tract disorders - Elevated levels of urea and creatinine in the blood (uremia). Formation of kidney stones (nephrolithiasis). Frequent urination.

General disorders and reactions at the injection site - Runny nose, fever.

Precautions and Warnings:

- you are taking certain medicines used to treat heart disease (for example, cardiac glycosides such as Digoxin);
- you suffer from sarcoidosis (a disease of the immune system in which an increased amount of vitamin D3 may be present in the body);
- You are taking medicines containing vitamin D3 or are eating food or milk fortified with vitamin D3;
- in all likelihood, you will spend a lot of time in the open sun during treatment with Detrimed;
- You are taking calcium supplements. Your doctor will monitor your blood calcium levels throughout your treatment with Detrimed to make sure it is not too high;

- you have kidney damage or disease. Your doctor may need to check your calcium and phosphorus levels in your blood.

Other drugs and the Detrimed:

Inform your doctor, pharmacist or nurse that you are taking, have recently taken, or may start taking any other medicines.

This is especially important if you are taking:

- drugs that affect the heart or kidneys, such as cardiac glycosides (eg Digoxin) or diuretics. When used simultaneously with vitamin D₃, these drugs can cause a significant increase in calcium levels in the blood and urine;
- drugs containing vitamin D₃ or eating foods or milk fortified with vitamin D₃, such as some milks fortified with vitamin D;
- Rifampicin, Isoniazid (to treat tuberculosis). Their intake may reduce the effectiveness of vitamin D.

The following drugs (due to their possible effect on the absorption of vitamin D₃):

- antiepileptic drugs (anticonvulsants), barbiturates;
- glucocorticosteroids (steroid hormones such as hydrocortisone or prednisone).

The following medicines may decrease the effectiveness of vitamin D₃:

- drugs that reduce blood cholesterol levels (for example, cholestyramine, cholestipol);
- medicines that reduce the level of calcium in the blood (for example, Calcitonin, Etidronate);
- some drugs used for weight loss that reduce the absorption of fats in the intestines (for example, Orlistat);
- some laxatives (eg liquid petroleum jelly);
- antacids containing magnesium or aluminum (used for heartburn and indigestion).

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, talk to your doctor or pharmacist before taking this medicine.

Pregnancy

If you have an increased need for vitamin D, do not take vitamin D supplements without medical supervision, as too much vitamin D can harm your baby.

Breastfeeding

No information available.

Fertility

No information available.

Packaging:

Detrimed is filled in 10 ml or 15 ml amber Glass Bottles with PE Cap/dropper (1 ml = 30drops) and Patient Information Leaflet completed in a Paperboard box.

Shelf life:

2 years.

Open containers should be used within 6 months.

Storage conditions:

Store at temperatures between 5°C to 25°C.

Store in original package in order to protect from light.

Regulatory status:

Prescription only.