STEROGYL 2,000,000 ul/100 ml

Ergocalciferol
Oral solution

Treatment and/or prophylaxis of vitamin D-deficient states.

**FORMS and PRESENTATIONS**

Oral solution 2,000,000 IU/100 ml (colorless): Dropper bottle of 20 ml (= 1000 drops).

**COMPOSITION**

Per drop
Ergocalciferol (INN) or vitamin D2 0.01 mg
equivalent to 400 IU
Excipients (alcoholic solution): hydroquinone, ethyl alcohol 96.2°, purified water. Alcohol titer (v/v): 90 %.
Ethanol content: 14 mg/drop.
1 ml of oral solution corresponds to 50 drops.

**INDICATIONS**

Prophylaxis and/or treatment of vitamin D deficiency.

**DOSEAGE AND ADMINISTRATION**

1 drop = 400 IU of vitamin D2 (= 10 μg of crystallized vitamin D).
Do not drink this medicinal product pure. Dilute it in water, milk or fruit juice.
Prevention of vitamin D deficiency:
It is generally accepted that prophylaxis of vitamin D deficiency must be:
Systematic:
in infants and young children,
in pregnant women (last trimester) and breastfeeding women, in late winter and springtime,
in the elderly,
eventually in children and adolescents if sun exposure is insufficient.
In the following conditions:
no sun exposure or dark skin with an unbalanced diet (low in calcium, vegetarians, etc.) or an extensive
dermatological condition or granulomatous disorder (tuberculosis, leprosy, etc.),
subjects taking anticonvulsants (barbiturates, phenytoins, primidone),
subjects on long-term corticosteroid therapy,
digestive pathologies (intestinal malabsorption and cystic fibrosis),
hepatic insufficiency.
The dosages are as follows:
In infants receiving vitamin D-enriched milk:
Intake of 400 to 1000 IU/day, equivalent to 1 to 2 drops per day.
In breastfeeding infants or those not receiving vitamin D-enriched milk, and in young children to 5 years:
Oral intake of 1000 to 2000 IU/day, equivalent to 2 to 5 drops per day.
In adolescents:
Oral intake of 400 to 1000 IU/day, equivalent to 1 to 2 drops during winter.
In pregnant women:
Oral intake of 400 to 1000 IU/day, equivalent to 1 to 2 drops during the last trimester of pregnancy,
when the last trimester of pregnancy begins during winter, or in case of no sun exposure.
In breastfeeding women:
Oral intake of 400 to 1000 IU/day, equivalent to 1 to 2 drops during winter or in case of no sun exposure.
This intake covers the needs of the mother but not those of the child, particularly if the child
was born in winter or spring to a mother who did not receive vitamin D supplementation.
In the elderly:
Oral intake of 400 to 2000 IU/day, equivalent to 1 to 5 drops per day.
In children or adults with a digestive disorder:
Oral intake of 1000 to 2000 IU/day, equivalent to 2 to 5 drops per day.
In children or adults with renal failure:
Oral intake of 400 to 2000 IU/day, equivalent to 1 to 5 drops per day to ensure adequate repletion of
native vitamin D.
In children or adults receiving anticonvulsant therapy:
Oral intake of 1500 to 4000 IU/day, equivalent to 3 to 10 drops per day.
In children or adults in the other special conditions described above:
Oral intake of 400 to 1000 IU/day, equivalent to 1 to 2 drops per day.
Treatment of vitamin D deficiency (rickets, osteomalacia, neonatal hypocalcemia):
Oral intake of 2000 to 4000 IU/day, equivalent to 5 to 10 drops, for 3 to 6 months.
Daily treatment cost: €0.02 (for 10 drops).
If there are doubts about compliance, prefer sequential oral administration.

**CONTRAINDICATIONS**
Hypersensitivity to any of the ingredients.
Hypercalcemia, hypercalciuria, calcium lithiasis.

**WARNINGS and PRECAUTIONS FOR USE**
Note: this medicinal product has an alcohol titer of 90°, or approximately 14 mg alcohol per drop.
To avoid potential overdosage, take into account the total intake of vitamin D in case of combination of several treatments containing this vitamin.
For indications requiring repeated high doses, monitor serum and urinary calcium and discontinue vitamin D intake if serum calcium exceeds 105 mg/ml (2.62 mmol/l) or if urinary calcium exceeds 4 mg/kg/day in adults or 4 to 6 mg/kg/day in children.

In case of high calcium intake, frequent monitoring of urinary calcium is essential.

**INTERACTIONS**
Drug interactions:
To be taken into consideration:
Thiazide diuretics: due to the risk of hypercalcemia, use the lowest recommended dosage and monitor serum calcium more frequently.

**PREGNANCY and LACTATION**
There are no teratogenicity studies available in animals.
Extensive clinical experience appears to rule out a potential for vitamin D to cause fetal toxicity or malformation. Therefore, vitamin D may be prescribed during pregnancy if necessary. When necessary, vitamin D may be prescribed during lactation.

**OVERDOSE**
Signs resulting from excessive intake of vitamin D or its metabolites:
Clinical signs:
headache, fatigue, anorexia, weight loss, cessation of growth; nausea, vomiting; polyuria, polydipsia, dehydration; hypertension;
calcium lithiasis, tissue calcifications, particularly renal and vascular;
renal insufficiency.
Biological signs:
hypercalcemia, hypercalciuria, hyperphosphatemia, hyperphosphaturia.
Treatment:
Discontinue the administration of vitamin D, reduce calcium intake, increase diuresis, abundant fluid intake.

**PHARMACODYNAMICS**
Vitamin D (A: alimentary tract and metabolism).
The essential role of vitamin D is in the intestine, where it increases the capacity to absorb calcium and phosphates, and in the skeleton, where it promotes mineralization (thanks to its direct actions on bone formation and its indirect actions involving the intestine, parathyroids and mineralized bone).

**PHARMACOKINETICS**
Vitamin D undergoes passive absorption from the small intestine and enters the systemic circulation through the lymph, incorporated in chylomicrons.
After absorption it binds to a specific binding protein which transports it to the liver where it is converted to 25-hydroxyvitamin D. The latter binds to the same binding protein which transports it to the kidneys for conversion to the active form, 1,25-dihydroxyvitamin D.
It is stored mainly in adipose tissue and muscle but also in blood. 25-hydroxyvitamin D bound to its transport protein is the major circulating form of vitamin D. Its half-life in the blood is 15 to 40 days.
Vitamin D and its metabolites are eliminated in the feces, either unchanged or as water-soluble metabolites (calcitriolic acid, glucurononoconjugates).

**STORAGE CONDITIONS**
Store at a temperature below 25 °C protected from light.

**PRESCRIPTION/SUPPLY/REIMBURSEMENT**
Marketing Authorization No. 309 982.6 (1960/97 revised 05. 05. 2000).
Price: €2.06 (1 20 ml bottle).
65% reimbursement by national health insurance. Healthcare establishments.