1.3 Summary Product Characteristics (SPC)
1.3.1 Product information for Health Professionals

Summary of product characteristics

1. NAME OF THE MEDICINAL PRODUCT

VITAMINA D_3 BIOFARM 18000 IU/ml oral drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One milliliter of oral drops, solution contains 0.45 mg cholecalciferol.
One milliliter of oral drops, solution contains 36 drops.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral drops, solution
Clear, oily, slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VITAMINA D_3 BIOFARM is indicated:
- in young children, in the first 2 years of life, for the prophylaxis of rickets;
- in the treatment of osteomalacia caused by vitamin D deficiency;
- in the supportive treatment of osteoporosis;
- in the prophylactic treatment of symptoms due to deficient digestive absorption of vitamin D (eg chronic intestinal diseases, biliary cirrhosis, gastrointestinal resection, etc.);
- in hypoparathyroidism.

4.2 Posology and method of administration

Posology

Prophylaxis of rickets in young children, first year of life: daily 1 drop VITAMINA D_3 BIOFARM (500 IU vitamin D_3); **in preterm infants**: daily 2 drops VITAMINA D_3 BIOFARM (1000 IU vitamin D_3).
These children will receive VITAMINA D_3 BIOFARM from the second week of life up to one year.
In the **second year of life** it is recommended to continue the administration of VITAMINA D_3 BIOFARM, especially in the winter months.

Treatment of osteomalacia caused by vitamin D deficiency: daily 5 drops VITAMINA D_3 BIOFARM (2500 IU vitamin D_3) 3 times a day. Treatment should be continued for 1 year.

Supportive treatment of osteoporosis: daily 2-6 drops VITAMINA D_3 BIOFARM (1000-3000 IU vitamin D_3).

Prophylactic treatment of symptoms due to deficient digestive absorption of vitamin D: daily 4-8 drops VITAMINA D_3 BIOFARM (2000-4000 IU vitamin D_3).

Treatment of hypoparathyroidism: the recommended dose varies between 10,000 and 20,000 IU of vitamin D_3 per day. Depending on the values of calcium, the daily dose will be 20-40 drops VITAMINA D_3 BIOFARM (10000-20000 IU vitamin D_3). If higher doses are required, the use of other preparations with higher concentrations is recommended. Serum and urinary calcium levels will be measured initially every 4-6 weeks and then every 3-6 months, the dose of the medicine being adjusted according to these values.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
Hypercalcemia
Hypercalciuria
Kidney stones present or in history
Prolonged immobilization
Sarcoidosis

4.4 Special warnings and precautions for use

Periodic determination of blood and urine calcium levels in patients with reduced mobility and in those with a repeated history of renal calculi (calcium stones).
In the elderly, in hypercholesterolemia, in hypothyroidism, high doses are not administered. In repeated high-dose treatments, serum calcium and urinary calcium should be monitored and administration should be discontinued when serum calcium exceeds normal and urinary calcium exceeds 300-400 mg/24 hours.
Caution in renal failure.

4.5 Interaction with other medicinal products and other forms of interaction

Phenytoin and barbiturates may decrease the effect of vitamin D_3.
Co-administration of glucocorticoids may reduce the effect of the vitamin D_3.
Concomitant treatment with vitamin D_3 and digitalis may increase the toxic potential of the latter; these patients should be monitored (EKG and calcium level).
Co-administration with thiazide diuretics increases the risk of hypercalcemia. Vitamin D_3 is associated with metabolites or analogues of vitamin D only in exceptional cases and with monitoring of serum calcium.
Other drug interactions may occur with concomitant use of: antacids containing aluminum or magnesium, anticonvulsants, hydantoin, primidone, calcitonin, ethidronate, gallium nitrate, pamidronate, plicamycin, cholestyramine, colestipol, mineral oils, liver enzyme inhibitors, phosphorous enzyme preparations.

4.6 Fertility, pregnancy and lactation

In the first trimester of pregnancy, cholecalciferol administration is associated with increased teratogenic/embryotoxic risk.
Due to the high content of vitamin D, this product is used during pregnancy and lactation only after analyzing the maternal benefit/fetal risk ratio. During pregnancy, overdose of cholecalciferol caused teratogenic effects in the animal.
In humans, overdose of cholecalciferol should be avoided as prolonged hypercalcemia may cause physical and mental retardation in children, supravalvular aortic stenosis, retinopathy.

4.7 Effects on ability to drive and use machines

VITAMINA D_3 BIOFARM does not affect your ability to drive or use machines.

4.8 Undesirable effects

The following convention was used to classify the frequency of reactions: very common (≥1/10); common (≥1/100 and <1/10); uncommon: (≥1/1000 and <1/100); rare (≥1/10000 and <1/1000); very rare (<1/10000); of unknown frequency (cannot be estimated from the available data).

Metabolic and nutritional disorders
Uncommon: hypercalcemia, hypercalciuria.

Gastrointestinal disorders
Rare: constipation, flatulence, nausea, abdominal pain, diarrhea.

Skin and subcutaneous tissue disorders
Rare: pruritus, transient rash, urticaria.

Reporting suspected adverse reactions
Reporting suspected adverse reactions after drug authorization is important. This allows continuous monitoring of the benefit/risk ratio of the drug. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system, details of which are published on the website of the National Agency for Medicines and Medical Devices http://www.anm.ro.

4.9 Overdose

Symptoms
Overdose is manifested by hypercalcemia and can be life threatening.
Depending on the dose and duration of treatment, severe and persistent hypercalcemia may occur, with acute manifestations (cardiac arrhythmias, nausea, vomiting, anorexia, constipation, asthenia, adynamia, headache, disturbances of consciousness) or chronic (polyuria, polydipsia, loss of appetite, weight loss, growth stagnation, kidney stones, nephrocalcinosis, extraosseous calcification - especially renal and vascular). In isolated cases, the evolution of these phenomena has been fatal.
Lab tests show hypercalcemia, hypercalciuria as well as elevated plasma concentrations of 25-hydroxycholecalciferol, hyperphosphataemia, hyperphosphaturia.

Treatment
There is no specific antidote.
Treatment consists of a low-calcium or calcium-free diet, water rebalancing, forced diuresis, and calcitonin administration.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vitamins, vitamins D and analogues; ATC code: A11CC05.

Vitamin D intervenes in the metabolism of calcium and phosphorus, increases calcium and decreases the excretion of the two substances in the feces. It stimulates the deposition of mineral salts in the bones, by activating phosphatase. High doses contribute to the mobilization of calcium in the bone with an increase in calcium in the blood and urine.
Vitamin D influences cellular metabolism, activates cellular respiratory processes.

5.2 Pharmacokinetic properties

Absorption
Vitamin D is well absorbed from the digestive tract (75%) in the presence of bile.

Distribution
It is stored in the liver, adrenal glands, lungs, kidneys, spleen. $T_{1/2}$ 960 hours.

Metabolism
Inactive cholecalciferol as such, undergoes various transformations in the body. It is hydroxylated in the liver with the formation of 25-hydroxicalciferol (25-HCC, calcifediol) the metabolite of vitamin D3 with the highest plasma concentration. It is transported bound to a specific protein. It has vitamin action. Calciferol is subsequently hydroxylated in the kidneys and converted to 1,25-dihydroxycholecalciferol (1,25-DHCC, calcitriol), which is the most active metabolite of vitamin D_3. Calcifediol has weaker effects. 1,25-DHCC biogenesis is regulated by parathyroid hormone, plasma phosphorus (stimulates) and calcitonin (inhibits). Alfacalcidol is inactive but is converted in the liver to calcitrol.

5.3 Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

All-rac-α-tocopheryl acetate
Medium-chain triglycerides

6.2 Incompatibilities

It's not necessary.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store below 30°C in its original packaging.
Use for a maximum of 180 days from the first opening of the bottle.

6.5 Nature and contents of container

Carton with one amber glass bottle with a dropper applicator, containing 10 ml oral drops, solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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10. DATE OF REVISION OF THE TEXT