

STEROGLYL 15A and 15H

Ergocalciferol

Prophylaxis and/or treatment of vitamin D deficiency.

FORMS and PRESENTATIONS

Sterogyl 15 "A":

Oral solution 600,000 IU/1.5 ml (alcohol-based, colorless): Ampoule-vial filled to 1.5 ml, unit pack.

Sterogyl 15 "H":

Oral and IM injection solution 600,000 IU/1.5 ml (oil-based, light yellow): Ampoule-vial filled to 1.5 ml, unit pack.

COMPOSITION

Sterogyl 15 "A":

per ampoule

Ergocalciferol (INN) 600,000 IU

Excipients: ethyl alcohol 96.2°, purified water. Inerting gas: nitrogen.

Alcohol titer (v/v): 89.8°.

Ethanol content: 1.06 g/amp.

Sterogyl 15 "H":

per ampoule

Ergocalciferol (INN) 600,000 IU

Excipient: groundnut oil. Inerting gas: nitrogen.

INDICATIONS

Treatment and prophylaxis of vitamin D-deficient states.

DOSAGE AND ADMINISTRATION

Dosage:

Restricted to adults.

This dosage form is not suitable for children due to its high vitamin D content.

½ to 1 ampoule (equivalent to 300,000 to 600,000 IU vitamin D2), in a single dose, once a year.

Treatment cost: Sterogyl 15 "A": €0.80 to €1.60; Sterogyl 15 "H": €0.85 to €1.69.

Method of administration:

Sterogyl 15 "A":

Do not drink this medicinal product pure. Dilute it in water or fruit juice.

Sterogyl 15 "H":

IM route.

The ampoule can also be administered by the oral route.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

Hypercalcemia, hypercalciuria, calcium lithiasis.

WARNINGS and PRECAUTIONS FOR USE

Sterogyl 15 "A": Note : this medicinal product has an alcohol titer of 90°, or approximately 1 g alcohol per ampoule. It is not recommended in patients with liver disease, alcoholism or epilepsy.

Sterogyl 15 "A" and "H":

This medicinal product contains a very high dose of vitamin D. To avoid potential overdose, do not administer more than once a year and avoid association with other treatments containing this vitamin.

Monitor serum and urinary calcium levels 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.

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

INTERACTIONS

Drug interactions:

Related to vitamin D2:

To be taken into consideration:

Thiazide diuretics: due to the risk of hypercalcemia, use the lowest recommended dosage and monitor serum calcium more frequently.

Related to the presence of alcohol (Sterogyl 15 "A"):

Inadvisable:

CNS depressants: morphinics (analgesics, antitussives and substitution treatments):

barbiturates; benzodiazepines; anxiolytics other than benzodiazepines; sedative antidepressants (amitriptyline, doxepine, mianserine, mirtazapine, trimipramine); neuroleptics; sedative H1 antihistamines; centrally acting antihypertensives; other: baclofen, pizotifen, thalidomide: alcohol increases the sedative effect of these substances. Impaired vigilance may make it dangerous to drive or use machines. Avoid consumption of alcoholic beverages and medications containing alcohol.

Non-selective MAO inhibitors (iproniazide): increase of the hypertensive and/or hyperthermic effects of tyramine present in certain alcoholic beverages (chianti, certain beers, etc.). Avoid consumption of alcoholic beverages and medications containing alcohol.

Insulin: increased hypoglycemic reaction (inhibition of compensation reactions which may facilitate the occurrence of hypoglycemic coma). Avoid consumption of alcoholic beverages and other medications containing alcohol.

Metformin: increased risk of lactic acidosis during acute alcohol intoxication particularly in case of:

- fasting or denutrition,
- hepatocellular insufficiency.

Avoid consumption of alcoholic beverages and other medications containing alcohol.

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INTERACTIONS (continued)

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Hypoglycemic sulfonylureas: antabuse effect, particularly for glibenclamide, glipizide, tolbutamide. Increased hypoglycemic reaction (inhibition of compensation reactions) which may facilitate the occurrence of hypoglycemic coma. Avoid consumption of alcoholic beverages and other medications containing alcohol.

Medicinal products that induce an antabuse reaction with alcohol: disulfiram, furazolidone, cefamandole, (cephalosporin antibacterial), chloramphenicol (phenicol antibacterial), glibenclamide, glipizide, (hypoglycemic sulfonylurea antidiabetic agents), griseofulvin (antifungal), metronidazole, ornidazole, secnidazole, tenonitroazole, tinidazole (5-nitro-imidazole antifungals), ketoconazole (azole antifungal), procarbazine (cytostatic): antabuse effect (hot flush, redness, vomiting, tachycardia). Avoid consumption of alcoholic beverages and other medications containing alcohol.

To be taken into consideration:

Oral anticoagulants: Possible variations in the anticoagulant effect:

- increase in case of acute intoxication.
- decrease in case of chronic alcoholism (due to increased metabolism).

PREGNANCY and LACTATION

At 600,000 IU vitamin D per ampoule, the vitamin D concentration in this medicinal product is high and does not correspond to the doses usually recommended during pregnancy. Therefore, this medicinal product should not be administered during either pregnancy or lactation.

DRIVING AND USING MACHINES

Sterogyl 15 "A": impaired vigilance, related to the presence of alcohol, may make it dangerous to drive or use machines.

UNDESIRABLE EFFECTS

Sterogyl 15 "H": due to the presence of groundnut oil, risk of hypersensitivity reaction (anaphylactic shock, urticaria).

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 on 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 (calcitric acid, glucuronoconjugates).

STORAGE CONDITIONS

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

PRESCRIPTION/SUPPLY/REIMBURSEMENT

LIST II

Marketing Authorization No. 309 983.2 (1943/97 revised 1998) "A".

309 985.5 (1940/97 revised 1998) "H".

Price: €1.60 (15 "A", 1 ampoule).

€1.68 (15 "H", 1 ampoule).