December 2023

SUMMARY OF PRODUCT CHARACTERISTIC (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Calvitalis Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each teaspoonful (5 mL) of the syrup contains:

Viatmin A Palmitate (1.7MIU/g) *	0.7050
Equivalent to Vit. A 1200 IU	
Cholecalciferol (40MIU/g) *	0.0025
Equivalent to Vit. D_3 100 IU	
Thiamine hydrochloride * (Vit. B_1 hydrochloride)	1.000
Riboflavin-5-sodium phosphate	1.000
(Vit. B_2 sodium phosphate	
Pyridoxine hydrochloride (Vit. B_6 hydrochloride)	0.500
Nicotinamide	5.000
Dexpanthenol	2.000
Alpha-tocopheryl acetate * (Vit. E acetate)	1.000
Ascorbic acid * (Vit. C)	50.000
Calcium lactate gluconate	40.000

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

Opalescent yellowish colour syrup, having orange flavoured and palatable taste.

4. CLINICAL PARTICULARS

4.1Therapeutic indications

Calvitalis syrup is generally used as a tonic, to improve well-being, to support organ function and for prophylaxis. It is usually recommended for use in the following conditions:

- for the prevention of vitamin deficiencies;
- for boosting the immune system;
- for the prevention of rickets and disturbances of development and growth;
- as a preventive measure in states of physical and mental exhaustion, such as poor concentration and school tiredness;
- for the prevention of loss of appetite and metabolic disorders;
- for the improvement of general well-being when recovering from illness (shorter convalescent period);
- for the promotion of the natural skin functions.

4.2 Posology and method of administration

Posology

- **Children below 4 years:** 1 teaspoonful (5mL) daily.
- **Children above 4 years and adults:** 2 teaspoonfuls (10mL) daily.

Method of Administration

For oral use

4.3 Contraindications

- It should not be taken by patients that have an allergy to any of its components.
- As with all preparations containing vitamin D; it should not be taken in hypercalcaemia (excess of calcium in the blood) or in hypercalciuria (excess of calcium in the urine.

4.4 Special warnings and precautions for use

In patients with renal calculus or Boeck's disease (sarcoidosis), **Calvitalis** should not be used for long periods in doses higher than those specified without medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of other vitamin A- or vitamin D-containing preparations may lead to vitamin A or vitamin D overdose, respectively.

4.6 Pregnancy and lactation

Pregnancy:

No problems have been reported with the intake of the daily recommended dosage.

The daily recommended dosage should not be exceeded, since vitamin A should not be taken in excessive doses (more than 5000 I.U) during pregnancy.

Lactation:

No problems have been reported with the intake of the daily recommended dosage.

4.7 Effects on ability to drive and use machines

There are no known effects on the ability to drive and to use machines.

4.8 Undesirable effects

Calvitalis syrup is generally well-tolerated when taken as prescribed. However, slight yellowish discoloration of the urine may occasionally occur. This is due to the vitamin B_2 (riboflavin) content of the preparation and is completely harmless.

4.9 Overdose

Doses in excess of those indicated, especially with concurrent use of other vitamin D-containing preparations, may lead to vitamin D overdose.
Induction of emesis and ingestion of activated charcoal are seldom necessary with acute ingestion unless extremely large amounts have been ingested. Symptomatic and supportive measures should be given as needed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calvitalis syrup is a well-balanced and well-formulated preparation containing calcium in addition to the 9 vitamins which are especially important during growth. It provides the body with the daily requirement of those essential constituents necessary to keep the vitality and health and to fight diseases.
Healthy people with balanced diets get enough supply of calcium and those vitamins. However, if the body need is not met with enough supply, cell functions will be impaired and symptoms of deficiency will start to appear. In such circumstances, **Calvitalis** will restore all functions to normal and the lost metabolic balance will be regained.

5.2 Pharmacokinetic properties

Most water-soluble vitamins as well as calcium are effective in the lower part of the range of benefits bind to carriers and are absorbed in the upper gastrointestinal tract.
The absorption of fat-soluble vitamins occurs in the intestinal wall. When passing bind to the carrier. At higher doses, the absorption of water-soluble vitamins by passive diffusion.
The fat-soluble vitamins need to bile acid resorption and are absorbed passively due to lipophilicity. The onset and extent of deficiency symptoms depends on the interaction of factors exogenous nature (type and variety of food, other food components, drug use) and endogenous factors (biological half-life, the immediate need, supply in the body, activating the body reserves).
Vitamin B is very rapidly converted to the coenzymes in the case of enteral absorption to some extent already in the mucosal surface of the intestinal cells.
The bioavailability can be affected by its own physiologically active substances and thus lead to significantly different concentrations in the blood.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Potassium sorbate
Citric acid
Sodium citrate
Sodium EDTA
Sodium saccharin
Xanthan gum
Glycerol
Sorbitol 70% solution
Liquid glucose
Malt extract
Tween 80 (polysorbate 80)
Cremophor RH 40 (polyoxyl 40 hydrogenated castor oil)
Sucrose
Orange flavour
Orange tangerine flavour
All fruits flavour
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store at a temperature of 15-25°C

6.5 Nature and contents of container

Packs of 150 mL and 300 mL syrup filled in glass bottle sealed with plastic cap and packed in a carton along with leaflet.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

06655/REN/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

October 16, 2020

10. DATE OF REVISION OF THE TEXT

02. February. 2017