Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ketovite Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Vitamin A (as palmitate) 2,500 IU
Ergocalciferol (Vitamin D_2) 400 IU
Cyanocobalamin 12.5 micrograms
Choline chloride 150 mg

Excipient(s) with known effect
5 ml solution contains 7.5 mg methyl parahydroxybenzoate (E218).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution (oral liquid).

A pale pink to yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a sugar-free therapeutic supplement for the prevention of vitamin deficiency in conditions such as galactosaemia, disaccharide intolerance, phenylketonuria and other disorders of carbohydrate or amino acid metabolism, as well as in patients who are on restricted, specialised or synthetic diets.

4.2 Posology and method of administration

Posology
For adults, children and the elderly: 5 ml daily.

Method of administration
For oral use.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Hypercalcaemia.

4.4 Special warnings and precautions for use

The recommended dose should not be exceeded without medical advice. No other vitamin supplement containing Vitamins A and D should be taken with Ketovite except under medical supervision.
Warning: do not exceed the stated dose.

Prolonged excessive ingestion of Vitamin A and Vitamin D can lead to hypervitaminosis states which may occur if foods high in this vitamin, (for example liver), are ingested in association with the recommended doses of this product.

Methyl parahydroxybenzoate
This medicinal product contains methyl parahydroxybenzoate (E218). May cause allergic reactions

(possibly delayed).

4.5 Interaction with other medicinal products and other forms of interactions

Absorption of some vitamins in this preparation may be reduced in conditions of fat malabsorption or with the concurrent use of neomycin, colestyramine, liquid paraffin, aminoglycosides, aminosalicylic acid, anticonvulsants, biguanides, chloramphenicol, cimetidine, colchicine, potassium salts and methyl-dopa. Serum B_{12} concentrations may be decreased by concurrent administration of oral contraceptives.

4.6 Fertility, pregnancy and lactation

Pregnancy
This product should not be used in pregnancy unless considered essential by the physician. Large doses of Vitamin A have been found to be teratogenic especially if administered during the first trimester of pregnancy.

Vitamin D given during the last trimester of pregnancy may cause hypercalcaemia in infants.

Breast-feeding
It is advised that if possible women receiving Vitamin D do not breastfeed their infants as this may lead to the development of hypercalcaemia in the infant.

4.7 Effects on ability to drive and use machines

Ketovite Liquid has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

None, in the absence of overdosage.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

Symptoms of overdosage may include anorexia, nausea, vomiting, rough dry skin, polyuria, thirst, loss of hair, painful bones and joints as well as raised plasma and urine calcium and phosphate concentration.

No emergency procedure or antidote is applicable and symptoms are rapidly reduced upon withdrawal of the preparation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combinations of vitamins, ATC code: A11JA.

The product is a multivitamin supplemental product.

5.2 Pharmacokinetic properties

The pharmacokinetics of the active substances would not differ from that of the same substance when derived naturally from oral foodstuffs.

5.3 Preclinical safety data

No relevant pre-clinical data has been generated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Saccharin
Methyl parahydroxybenzoate (E218)
Polysorbate 80
Ascorbic acid
α-tocopherol
Terpeneless orange oil
Ammonia solution, concentrated
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).

6.5 Nature and contents of container

Amber glass bottle with tamper-evident child-resistant closure.

Pack sizes: 100 ml, 140 ml or 150 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Taw Pharma (Ireland) Ltd
104 Lower Baggot Street
Dublin 2
D02 Y940
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23081/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 November 1987

Date of last renewal: 09 November 2007

10 DATE OF REVISION OF THE TEXT

January 2022