

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)	2500	IU
Ergocalciferol (Vitamin D ₂)	400	IU
Cyanocobalamin	12.5	micrograms
Choline chloride	150.0	mg

Excipients: also includes methyl parahydroxybenzoate (E218) 7.5mg/5ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution (oral liquid)
Pale pinkish clear to opalescent 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

For adults, children and the elderly: 5 ml daily, by oral administration.

4.3 Contraindications

Hypersensitivity to the product. 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 Liquid except under medical supervision.

The methyl parahydroxybenzoate (E218) in Ketovite Liquid may cause allergic reactions which can be delayed.

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.

4.5 Interaction with other medicinal products and other forms of interaction

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, aminosalicic acid, anticonvulsants, biguanides, chloramphenicol, cimetidine, colchicine, potassium salts and methyl-dopa. Serum B₁₂ concentrations may be decreased by concurrent administration of oral contraceptives.

4.6 Fertility, pregnancy and lactation

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.

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

None known.

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

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IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@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

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

Methylcellulose
Saccharin
Methyl Parahydroxybenzoate (E218)
Polysorbate 80
Ascorbic acid
Alpha tocopherol
Terpeneless Orange Oil
Strong Ammonia Solution
Purified Water

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 plastic screw cap containing 100 ml, 140 ml or 150 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Essential Pharmaceuticals Limited
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UK

8 MARKETING AUTHORISATION NUMBER

PA 1806/1/1

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

April 2015