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.

In order to achieve complete vitamin supplementation Ketovite Liquid should be used in conjunction with Ketovite Tablets.

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.

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 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, 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

Caution should be used in pregnancy as excessive doses of Vitamin A may be teratogenic, especially when taken in the first trimester.

Breast-feeding

Large doses of Vitamin D in lactating mothers may cause hypercalcaemia in infants.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Rosemont Pharmaceuticals Ltd
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Braithwaite Street
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LS11 9XE
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00427/0283

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation granted: 30 January 1990
Renewal granted: 9 September 2005

10 DATE OF REVISION OF THE TEXT

08/02/2022