

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ketovite Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains;

Thiamine hydrochloride	1.0	mg
Riboflavin	1.0	mg
Pyridoxine hydrochloride	0.33	mg
Nicotinamide	3.3	mg
Calcium pantothenate	1.16	mg
Ascorbic acid	16.6	mg
all-rac-Alpha-Tocopheryl acetate	5.0	mg
Inositol	50.0	mg
Biotin	0.17	mg
Folic acid	0.25	mg
Acetomenaphthone	0.50	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets.

Yellow tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vitamin 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 over 4 years, and the elderly: One tablet three times daily, by oral administration.

4.3 Contraindications

Hypersensitivity to the product.

4.4 Special warnings and precautions for use

The recommended dose should not be exceeded without medical advice

4.5 Interaction with other medicinal products and other forms of interaction

Pyridoxine may increase the peripheral metabolism of levodopa reducing therapeutic efficiency in patients with Parkinson's disease.

4.6 Fertility, pregnancy and lactation

The product should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

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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Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

4.9 Overdose

Overdosage of water-soluble vitamins would be rapidly excreted on cessation of dosage.

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

Heavy magnesium carbonate

Magnesium stearate

Magnesium trisilicate
Stearic acid
Methylcellulose
Colloidal anhydrous silica

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

LDPE plastic tablet container with cap containing 84, 90, 100 or 500 tablets.

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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Crabtree Road
Egham
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UK

8 MARKETING AUTHORISATION NUMBER

PA 1806/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th March 1988

Date of last renewal: 9th November 2007

10 DATE OF REVISION OF THE TEXT

April 2015