

# 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 the 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

#### Posology

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

### 4.3 Contraindications

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

### 4.4 Special warnings and precautions for use

The recommended dose should not be exceeded without medical advice.

#### Interference with clinical laboratory tests

Biotin may interfere with laboratory tests that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results, depending on the assay. The risk of interference is higher in children and patients with renal impairment and increases with higher doses. When interpreting results of laboratory tests, possible biotin interference has to

be taken into consideration, especially if a lack of coherence with the clinical presentation is observed (e.g. thyroid test results mimicking Graves' disease in asymptomatic patients taking biotin or false negative troponin test results in patients with myocardial infarction taking biotin). Alternative tests not susceptible to biotin interference should be used, if available, in cases where interference is suspected. The laboratory personnel should be consulted when ordering laboratory tests in patients taking biotin.

#### 4.5 Interaction with other medicinal products and other forms of interactions

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

Ketovite Tablets have no or negligible influence on the ability to drive and use machines.

#### 4.8 Undesirable effects

##### Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions
Immune system disorders	Not known (cannot be estimated from the available data)	Anaphylactic reaction

##### 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

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto: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.

Pharmacotherapeutic group: Vitamin B-complex, other combinations

ATC code: A11EX

### 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**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Essential Pharmaceuticals Limited  
Vision Exchange Building  
Trig it-Territorjals, Zone 1  
Central Business District  
Birkirkara, CBD 1070  
Malta

## **8 MARKETING AUTHORISATION NUMBER**

PA22662/002/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 7<sup>th</sup> March 1988

Date of last renewal: 9<sup>th</sup> November 2007

**10 DATE OF REVISION OF THE TEXT**

August 2020