

Ketovite Tablets

Multivitamin preparation

Read all of this leaflet carefully before you start taking this medicine. It contains important information for you.

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
 - There are usually no undesirable effects after taking Ketovite Tablets.
- If you do notice any unexpected effects, stop taking the tablets and tell your doctor or pharmacist.

In this leaflet:

1. What Ketovite Tablets are, and what they are used for
2. Before you take Ketovite Tablets
3. How to take Ketovite Tablets
4. Possible side effects
5. How to store Ketovite Tablets
6. Further information

1. WHAT KETOVITE TABLETS ARE, AND WHAT THEY ARE USED FOR

Ketovite Tablets are a therapeutic vitamin supplement for the prevention of vitamin deficiency. It is used in conditions such as:

- galactosaemia (a disorder of milk sugar digestion)
- disaccharide intolerance (a reaction to sugars such as sucrose, lactose and maltose)
- phenylketonuria (an inability to digest one of the essential amino acids)
- in other disorders of starch, sugar or amino acid metabolism
- in patients who are on restricted, specialised or synthetic diets

Ketovite Tablets are a multivitamin preparation, intended for use at the same time as Ketovite Liquid.

2. BEFORE YOU TAKE KETOVITE TABLETS

Do not take Ketovite Tablets if you

- are **allergic** (hypersensitive) to **any of the ingredients** of the tablets (see list in section 6 'Further information')

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- In particular, if you are being **treated for Parkinson's disease** with **medicines containing levodopa**, make sure your doctor knows of this, as one of the vitamins in Ketovite Tablets may reduce the activity of levodopa.

Pregnancy and breast-feeding

If you are pregnant talk to your doctor before taking Ketovite Tablets; you should only take them if he specifically tells you that you can.

Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO TAKE KETOVITE TABLETS

Dosage: Always take Ketovite Tablets exactly as your doctor has told you to.

You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults, children over 4 years of age and the elderly is one tablet three times a day.

If you take more Ketovite Tablets than you should

Ask the advice of your doctor or pharmacist.

If you forget to take Ketovite Tablets

Take your tablet as soon as you remember, but if this is within an hour or so of your next dose being due then leave out the forgotten dose and take your next dose at the right time. Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

There are usually no undesirable effects after taking Ketovite Tablets.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. HOW TO STORE KETOVITE TABLETS

Keep out of the reach and sight of children.

Do not use Ketovite Tablets after the expiry date which is stated on the pack after **Use By**. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ketovite Tablets contain

The active ingredients are thiamine hydrochloride (1mg), riboflavin (1mg), pyridoxine hydrochloride (0.33mg), nicotinamide (3.3mg), calcium pantothenate (1.16mg), ascorbic acid (16.6mg), acetomenaphthone (0.5mg), all-rac-alpha-tocopheryl acetate (5mg), inositol (50mg), biotin (0.17mg), and folic acid (0.25mg).

The other ingredients are heavy magnesium carbonate, magnesium stearate, magnesium trisilicate, stearic acid, methylcellulose and colloidal anhydrous silica.

What Ketovite Tablets look like and contents of the pack

Ketovite Tablets are small yellow tablets without markings. Ketovite Tablet packs contain 100 tablets.

Marketing authorisation holder and manufacturer

The Marketing Authorisation for Ketovite Tablets is held by Essential Pharmaceuticals Ltd, 7 Egham Business Village, Egham, Surrey, TW20 8RB, UK.

The tablets are manufactured by Dales Pharmaceuticals Ltd, Skipton, North Yorkshire, BD23 2RW, UK.

This leaflet was last approved in January 2015