



Package leaflet: Information for the user

KetTab-PL-IE-5

Ketovite Tablets

Multivitamin preparation

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Ketovite Tablets are and what they are used for
2. What you need to know before you take Ketovite Tablets
3. How to take Ketovite Tablets
4. Possible side effects
5. How to store Ketovite Tablets
6. Contents of the pack and other 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. What you need to know before you take Ketovite Tablets

Do not take Ketovite Tablets:

- if you are **allergic to any of the ingredients** of the tablets (listed in section 6).

Warnings and precautions

- Ketovite Tablets contains 0.17 mg biotin per tablet. If you are about to undergo laboratory testing you must tell your doctor or the laboratory personnel that you are taking or have recently taken Ketovite Tablets, because biotin may affect results of such tests. Depending on the test, the results may be falsely elevated or falsely low due to biotin. Your doctor may ask you to stop taking Ketovite Tablets before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin and affect the results of laboratory tests. Please inform your doctor or the laboratory personnel, if you are taking such products.

Other medicines and Ketovite Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ketovite Tablets.

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.

3. How to take Ketovite Tablets

Always take Ketovite Tablets exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended 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

Like all medicines, this product can cause side effects, although not everybody gets them. The following side effect has been reported but the frequency cannot be estimated from the available information (frequency not known):

- severe allergic reaction (anaphylactic reaction).

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.

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5. How to store Ketovite Tablets

Keep Ketovite Tablets out of the sight and reach of children.

Store in a refrigerator (2°C - 8°C).

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ketovite Tablets contain

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

Marketing Authorisation Holder

Essential Pharmaceuticals Ltd,

Vision Exchange Building, Triq it-Territorjals, Zone 1,
Central Business District, Birkirkara, CBD 1070, Malta.

Manufacturer

Dales Pharmaceuticals Ltd,

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