

Package leaflet: Information for the user

Ketovite Liquid

Multivitamin preparation

Read all of this leaflet carefully before you start taking this medicine. 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 Liquid is and what it is used for
2. What you need to know before you take Ketovite Liquid
3. How to take Ketovite Liquid
4. Possible side effects
5. How to store Ketovite Liquid
6. Contents of the pack and other information

1. WHAT KETOVITE LIQUID IS, AND WHAT IT IS USED FOR

Ketovite Liquid is a sugar-free therapeutic supplement for the prevention of vitamin deficiency. It is used in conditions such as:

- galactosemia (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 Liquid is a multivitamin preparation, intended for use at the same time as Ketovite Tablets.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KETOVITE LIQUID

Do not take Ketovite Liquid

- If you are **allergic** to the active substances or **any of the ingredients** of this medicine (listed in section 6).
- If you have **hypercalcaemia** (high blood calcium level).
- If you are taking **other vitamin preparations**, especially those containing Vitamins A and D, such as cod-liver oil.

Warnings and precautions

- If you have trouble digesting fatty foods as the absorption of some of the vitamins may be reduced.

Other medicines and Ketovite Liquid

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking an **oral contraceptive** pill as “The Pill” may reduce Vitamin B₁₂ blood levels.

Absorption of some of the vitamins in Ketovite Liquid may be reduced if you are also taking:

- neomycin
- colestyramine
- liquid paraffin
- aminoglycosides
- aminosalicic acid
- anticonvulsants
- biguanides
- chloramphenicol
- cimetidine
- colchicine
- potassium salts
- methyldopa

Ask your doctor or pharmacist for advice.

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 this medicine.

It is not recommended to use this medicine if you are pregnant or likely to become pregnant. Large doses of Vitamin A may damage the baby if taken during the first three months of pregnancy.

If you are breast-feeding, large amounts of Vitamin D may cause poor bone formation in your baby.

Ketovite Liquid contains methyl parahydroxybenzoate

This medicine contains **methyl parahydroxybenzoate** (E218), which may cause allergic reactions (possibly delayed).

3. HOW TO TAKE KETOVITE LIQUID

Always take this medicine exactly as described in this leaflet or as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 5 ml daily. Shake before use.

If you take more Ketovite Liquid than you should

Do not take more than you have been prescribed or than is recommended, as this may lead to too high a dose level, particularly of Vitamin A and Vitamin D.

If you forget to take Ketovite Liquid

You may take the dose later on during the same day. Do not take a double dose to make up for a forgotten dose.

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 medicine can cause side effects, although not everybody gets them.

There are usually no side effects after taking Ketovite Liquid.

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.

United Kingdom

Yellow Card Scheme

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

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

5. HOW TO STORE KETOVITE LIQUID

Keep this medicine out of the sight and reach of children.

Do not use Ketovite Liquid after the expiry date which is stated on the bottle after **Exp.** The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

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 Liquid contains

The active substances are vitamin A (as palmitate) 2,500 IU, ergocalciferol (vitamin D₂) 400 IU, cyanocobalamin 12.5 micrograms and choline chloride 150 mg, in each 5 ml.

The other ingredients are hypromellose, saccharin, methyl parahydroxybenzoate (E218), polysorbate 80, ascorbic acid, α-tocopherol, terpeneless orange oil, concentrated ammonia solution and purified water. See section 2 for further information on methyl parahydroxybenzoate.

What Ketovite Liquid looks like and contents of the pack

Ketovite Liquid is a pale pink to yellow oral liquid which you take by mouth (oral use).

Ketovite Liquid is available in bottles of 100 ml, 140 ml and 150 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

The Marketing Authorisation for Ketovite Liquid in Ireland is held by Taw Pharma (Ireland) Ltd, 104 Lower Baggot Street, Dublin 2, D02 Y940, Ireland.

The Marketing Authorisation for Ketovite Liquid in UK is held by Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

Manufacturer

Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, The Netherlands.

This leaflet was last revised in December 2021