

PACKAGE LEAFLET: INFORMATION FOR THE USER

COBALAMIN

500µg film-coated tablet

MECOBALAMIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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2. Before you take COBALAMIN
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1. WHAT COBALAMIN IS AND WHAT IT IS USED FOR

COBALAMIN tablets contain Mecobalamin which is a form of vitamin B 12, and it is used to treat peripheral neuropathy (damage to peripheral nerves which results in pain, numbness, and tingling, swelling, redness). B 12 is found in blood and cerebrospinal fluid. Mecobalamin plays an important role in various metabolic functions, including the metabolism of fat and carbohydrates, and protein synthesis. Mecobalamin prevents the degradation of nerve fibers in case of neuropathy and accelerates the regeneration of nerve tissue. It is used for the treatment of numbness, pain and paralysis caused by peripheral neuropathies including diabetic neuropathy and polyneuritis (inflammation of nerves resulting in pain).

2. BEFORE YOU TAKE COBALAMIN

Do not take COBALAMIN

- if you are allergic (hypersensitive) to Mecobalamin, other compounds of vitamin B12 including cyanocobalamin and hydroxocobalamin, cobalt or to any of the other ingredients in this medicine

Take special care with COBALAMIN, so you must tell the doctor if you

- If you are sensitive to other preparations of cobalamin (which are naturally present in certain types of food), you could be sensitive to vitamin B12 preparations, including mecobalamin.
- Efficient use of Mecobalamin should be estimated after several months of application. If the desired response is not achieved, treatment should be stopped.
- Mecobalamin therapy is not recommended for people who work with mercury or mercury derivatives.

Taking other medicines

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

There have not been reported significant interactions with other medicines when taking cobalamin tablets. However, the gastrointestinal absorption of vitamin B12 preparations in general can be reduced with simultaneous administration of colchicine, aminoglycoside antibiotics, aminosalicic acid and its salts and excessive alcohol use over a period longer than 2 weeks.

The impact on the results of clinical and laboratory tests

Methotrexate, pyrimethamine and the majority of anti-infective drugs prevent the implementation of microbiological diagnostic blood tests for preparations of vitamin B12.

Pregnancy and breastfeeding

Trials have not been performed on humans. Animal studies do not indicate teratogenicity or harmful effects on the fetus. Mecobalamin is excreted into breast milk. For this reason, the use of COBALAMIN is not recommended during pregnancy and breastfeeding.

Driving and using machines

COBALAMIN should not affect your ability to drive and use machines.

Important information

COBALAMIN tablets contain milk sugar (lactose). So if you suffer from some form of sugar intolerance, tell your doctor before taking this medication.

3. HOW TO TAKE COBALAMIN

The usual dose for adults is 3 tablets per day in 3 divided doses. The dose can be adjusted depending on the age and symptoms of the patient.

If you take more COBALAMIN than you should

Vitamin B12 preparations are generally not toxic even at higher doses.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Mecobalamin is well tolerated. Like all medicines, COBALAMIN can cause side effects, although not everybody gets them.

Rare cases of gastrointestinal side effects such as anorexia (loss of appetite), nausea, vomiting and diarrhea, and rare cases of rash.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of suspected 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.

5. HOW TO STORE COBALAMIN

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use COBALAMIN after the expiry date which is stated on the label, 3 years from the date of manufacture.

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 COBALAMIN contains

The active substance is Mecobalamin.

Each film-coated tablet contains Mecobalamin (methylcobalamin) 500µg.

Other ingredients are lactose, corn starch, povidone K30, and magnesium stearate. For coating: hydroxypropyl methylcellulose type 2910 (Methocel E5), polyethylene glycol, titanium dioxide, white beeswax.

What COBALAMIN looks like and contents of the pack

Cobalamin are white, round, biconvex film-coated tablets.

Box with 30 tablets in blister made of aluminum foil.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Manufacturer

FARMAVITA d.o.o. SARAJEVO

Igmanska 5a, Vogošća, Sarajevo, Bosna i Hercegovina.

Manufacturer of the medicinal product

FARMAVITA d.o.o. SARAJEVO in cooperation with Jordanian Pharmaceutical Manufacturing Co (JPM) Jordan

Igmanska 5a, Vogošća, Sarajevo, Bosna i Hercegovina.