



**Adicobal® 500**  
500 µg Mecobalamin  
film-coated tablets

**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. See section 4.

**What is in this leaflet?**

1. What Adicobal® is and what it is used for
2. What you need to know before you take Adicobal®
3. How to take Adicobal®
4. Possible side effects
5. How to store Adicobal®
6. Contents of the pack and other information

**1. What Adicobal® is and what it is used for**

Adicobal® contains Mecobalamin and is a kind of endogenous coenzyme B12:

As a coenzyme of methionine synthetase, mecobalamin plays an important role in transmethylation in the synthesis of methionine from homocysteine.

- Mecobalamin is well transported to nerve cell organelles, and promotes nucleic acid and protein synthesis:  
Experiments in rats show that mecobalamin is better transported to nerve cell organelles than cyanocobalamin and promotes nucleic acid and protein synthesis more than cobamamide does. Experiments with cells from the brain origin and spinal nerve cells in rats also show mecobalamin to be involved in the synthesis of thymidine from deoxyuridine, promotion of deposited folic acid utilization and metabolism of nucleic acid.
- Mecobalamin promotes axonal transport and axonal regeneration.  
In rat models with streptozotocin-induced diabetes mellitus, mecobalamin normalizes axonal skeletal protein transport in sciatic nerve cells. Mecobalamin exhibits neuropathologically and electrophysiologically inhibitory effects on nerve degeneration in neuropathies induced by drugs, such as adriamycin, acrylamide, and vincristine (in rats and rabbits), models of axonal degeneration in mice and neuropathies in rats with spontaneous diabetes mellitus.
- Mecobalamin promotes myelination (phospholipid

synthesis):

Mecobalamin promotes the synthesis of lecithin which is the main constituent of medullary sheath lipid. It also increases myelination of neurons in rat tissue culture more than cobamamide does.

- Mecobalamin restores delayed synaptic transmission and diminished neurotransmitters back to normal: Mecobalamin restores end-plate potential induction early by increasing nerve fiber excitability in the crushed sciatic nerve in rats. In addition, mecobalamin normalizes diminished levels of acetylcholine in brain tissue of rats fed with a choline-deficient diet.

**Indication**

Peripheral neuropathies

**2. What you need to know before you take Adicobal®**

**Do not take Adicobal®**

- if you are allergic to Mecobalamin or any of the other ingredients of this medicine (listed in section 6);

If you think any of these apply to you, or if you are in doubt, ask your doctor for advice before taking Adicobal®.

**Warnings and precautions**

**This product should not be used aimlessly for more than one month unless it is effective.**

Vitamin B12 should, if possible, not be given to patients with suspected vitamin B12 deficiency without first confirming the diagnosis. Where it is desirable to start therapy immediately, combined treatment for both deficiencies may be started once suitable samples have been taken to permit diagnosis of the deficiency, and the patient converted to the appropriate treatment once the cause of the anaemia is known. Regular monitoring of the blood is advisable.

Although the haematological symptoms of B12 deficiency and folate deficiency are similar, it is important to distinguish between them since the use of folate alone in B12-deficient megaloblastic anaemia can improve haematological symptoms without preventing aggravation of accompanying neurological symptoms, and may lead to severe nervous system sequelae such as subacute combined degeneration of the spinal cord. Use of doses greater than 10 micrograms daily may produce a haematological response in patients with folate deficiency and indiscriminate use may mask the precise diagnosis. Conversely, folate may mask vitamin B12 deficiency.

**Precautions concerning use:**

Administration: Mecobalamin is susceptible

to photolysis. Light decreases the content of mecobalamin and tablets may change colour with exposure to moisture. Therefore, this product should be used promptly after the package is opened, and caution should be taken so as not to expose the tablets to light/moisture.

### **Other Precautions**

The prolonged use of larger doses of mecobalamin is not recommended for patients whose occupation requires the handling of mercury or mercury compounds.

### **Other medicines and Adicobal®**

Absorption of vitamin B12 from the gastrointestinal tract may be reduced by neomycin, aminosalicic acid, histamine H2-antagonists, omeprazole, and colchicine.

Serum concentrations may be decreased by use of oral contraceptives.

Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations.

### **Pregnancy and Lactation**

#### **Pregnancy**

There are no data available for mecobalamin to be used in pregnant women.

#### **Lactation**

There are no data available for mecobalamin to be used in lactating women. However, since vitamin B12 is distributed into breast milk, The American Academy of Pediatrics considers its use to be usually compatible with breast feeding.

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

### **3. How to take Adicobal®**

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

### **Adult Dosage**

The usual adult dosage for oral use is 3 tablets (1,500 µg of mecobalamin) daily divided into three doses. The dosage may be adjusted depending on the patient's age and symptoms.

### **Mode of administration**

Oral.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dermatologic Effects: Rash ; In the event of such symptoms, treatment should be discontinued.

Gastrointestinal Effects: Anorexia, nausea/vomiting and diarrhea

Neurologic Effects (Central nervous system): Headache

Others:

Anaphylactoid reaction: decrease in blood pressure or dyspnea, may occur. Patients should be carefully observed. In the event of such symptoms, treatment should be discontinued immediately and appropriate measures taken.

Hot sensation

Diaphoresis

In addition, your doctor may identify changes in your blood or urine test results.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Adicobal®**

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

Do not use this medicine after the expiry date which is stated on the pack after "EXP".

Store below 30 °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 Adicobal® contains**

The active substance is Mecobalamin. Each tablet contains 500 µg Mecobalamin.

The other ingredients are:

- Tablet core: lactose monohydrate, microcrystalline cellulose; magnesium stearate and silica colloidal anhydrous.
- Film coating: polyvinyl alcohol; talc; methacrylic acid and ethyl acrylate copolymer; polyethylene glycol; sodium bicarbonate; titanium dioxide (E171); iron oxide red (E172); allura red AC aluminum lake (E129); sunset yellow FCF aluminum lake (E110).

#### **What Adicobal® looks like and contents of the pack**

Red, oblong film-coated tablet.

Pack size:

The tablets are placed in blisters containing 15 tablets. 2 (two) blisters with a leaflet in carton box.

#### **Marketing Authorisation Holder and Manufacturer**

Adipharm EAD

130, Simeonovsko shosse Blvd., 1700 Sofia  
Bulgaria

**This leaflet was last revised in February 2018.**