

## Package leaflet: Information for the patient

### Betolvex 1 mg film-coated tablets

Cyanocobalamin

<[Prescription only:]>

**<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.>

<[Non-prescription:]>

**<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, pharmacist, or nurse has 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.>

<[To be completed nationally]>

#### What is in this leaflet

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

#### 1. What Betolvex is and what it is used for

Vitamin B<sub>12</sub> is a vital vitamin which is needed e.g. for normal cell division, normal production of blood and normal neurological function. Lack of Vitamin B<sub>12</sub> can e.g. result in the blood deficiency disease pernicious anemia and/or symptoms from the neurological system, for example sensory disturbances. Normally vitamin B<sub>12</sub> is provided in small amounts with food. It is absorbed by the body through e.g. the gastric acid and a special protein (intrinsic factor) which is formed in the gastric mucous. If the intake of pure vitamin B<sub>12</sub> is increased 100-fold (=1 tablet of Betolvex) sufficient amounts of vitamin can be absorbed by the body despite of disturbances in the gastrointestinal function.

Betolvex is administrated at vitamin B<sub>12</sub> deficiency and when there is a risk for deficiency to occur. For example, vitamin B<sub>12</sub> deficiency can develop if the vitamin cannot be absorbed normally by the body from foods. This can be due to a gastrointestinal disease but can also result from a stomach ulcer operation or other intestinal surgery. Vitamin B<sub>12</sub> deficiency can also occur due to longterm medicinal treatment of gastrointestinal inflammation.

<[Non-prescription:]><You must talk to a doctor if you do not feel better or if you feel worse.>

## 2. What you need to know before you take Betolvex

### Do not take Betolvex:

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

### Other medicines and Betolvex

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

The absorption of vitamin B<sub>12</sub> may be affected by:

- aminoglycosides (antibiotic)
- aminosalicic acid (antibiotic)
- antiepileptics (medicine used to treat epilepsy)
- biguanides (medicine used to treat diabetes)
- chloramphenicol (antibiotic)
- cholestyramine (medicine used to reduce the amount of cholesterol (fats) in the blood)
- potassium salts (used to correct potassium deficiency)
- methyldopa (medicine used to treat high blood pressure)
- gastric acid inhibiting substances (for example omeprazole and cimetidine).

### 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.

No harmful effects on the fetus or breast-fed children has been identified.

## 3. How take take Betolvex

<[Prescription only:]>

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

<[Non-prescription only:]>

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

The dose should be decided by your doctor, who will adjust it individually for you.

The recommended dose for adults is: 1 tablet daily. In the beginning of treatment a higher dose is often prescribed.

The tablet should preferably be taken on an empty stomach.

### If you take more Betolvex than you should

If you have taken more tablets than you should, contact your doctor, hospital or the local poisons information centre.

### If you stop taking Betolvex

Treatment with vitamin B<sub>12</sub> must be continued throughout life if it is due to a chronic decreased uptake from the intestines. It is important that you do not stop taking the tablets even if you feel healthy. Otherwise the deficiency will eventually come back.

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

## 4. Possible side effects

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

**Stop taking Betolvex and immediately contact your doctor if you get any of the following symptoms (angioedema)**

- Swelling of face, tongue and/or throat
- Difficulties swallowing
- Rash and breathing difficulties

These side effects are rare (may affect up to 1 in 1,000 people).

The following side effects have also been reported with Betolvex:

**Rare side effects** (may affect up to 1 in 1,000 people)

- Allergic reactions including itching and swelling.
- Fever.
- Rash.
- Hives.

**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 [To be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Betolvex**

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 carton 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.

This medicine does not require any special storage conditions.

**6. Contents of the pack and other information**

**What Betolvex contains**

- The active substance is: Cyanocobalamin 1 mg (vitamine B<sub>12</sub>).
- The other excipients are: Mannitol, pregelatinised starch, potato starch, microcrystalline cellulose, magnesium stearate, stearic acid. Film-coating: Hypromellose (E464), macrogol 400, titanium dioxide (colouring agent E 171), red iron oxide.

**What Betolvex looks like and contents of the pack**

The tablet is pink, round, convex with a diameter of 8 mm, marked CCO.

Bottle: 30, 60, 100 tablets

1000 tablets (for dose dispensing and hospital use only)

Blister: 50x1, 98x1 tablet (for hospital use only)

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

<[To be completed nationally]>

**Manufacturer**

Merckle GmbH  
Ludwig-Merckle-Str. 3  
89143 Blaubeuren  
Germany

**This leaflet was last revised in 2023-06-22**