

Package leaflet: Information for the patient

Betolvan 1 mg film-coated tablets

cyanocobalamin (vitamin B₁₂)

[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, pharmacist or nurse. 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 Betolvan is and what it is used for
2. What you need to know before you take Betolvan
3. How to take Betolvan
4. Possible side effects
5. How to store Betolvan
6. Contents of the pack and other information

1. What Betolvan is and what it is used for

Betolvan contains the active substance cyanocobalamin, vitamin B₁₂. This is a vital vitamin which is needed e.g. for normal production of blood and normal neurological function.

Betolvan is administered at vitamin B₁₂ deficiency or when there is a risk for vitamin B₁₂ deficiency to occur.

For example, vitamin B₁₂ 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 B₁₂ 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.

Cyanocobalamin found in Betolvan may also be approved to treat other conditions not mentioned in this product information. Ask your doctor, pharmacist or other healthcare professional if you have any further questions and always follow their instructions.

2. What you need to know before you take Betolvan

Do not take Betolvan:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Betolvan.

At the start of treatment, your clinical condition must be diagnosed by a doctor to clarify the underlying cause of your deficiency. This includes checking your gastrointestinal function. The doctor will decide whether or not you are getting enough vitamin B12 from food and whether oral supplementation with Betolvan is necessary.

Based on the severity of your condition, your doctor will monitor your response to this medicine in the first months of treatment. This will be done with blood tests. If you follow the treatment plan carefully, treatment could be life-long, depending on your underlying condition.

If you have severely impaired renal function the dosage of Betolvan may need to be adjusted.

If you also have a folic acid deficiency, this may hamper your response to therapy. In this case, the use of Betolvan must be accompanied by treatment of your folic acid deficiency.

Other medicines and Betolvan

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

The absorption of vitamin B₁₂ may be affected by:

- oral contraceptives
- 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)
- methyl dopa (medicine used to treat high blood pressure)
- gastric acid inhibiting substances (for example omeprazole and cimetidine).

Pregnancy and breast-feeding

There are no known risks of using vitamin B₁₂ during pregnancy.

The drug passes into breast milk, but no effects on the breastfed baby are expected if you use the recommended dose of the drug.

Driving and using machines

Betolvan has no or negligible influence on the ability to drive or use machines.

3. How to take Betolvan

[Prescription only:]

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

[Non-prescription:]

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

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

The recommended maintenance dose for adults is: 1 tablet daily. In the beginning of treatment a higher dose is often prescribed, which is then reduced to the maintenance dose.

The tablet should preferably be taken on an empty stomach. The tablet can be swallowed whole, divided or crushed.

If you take more Betolvan than you should

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

If you forget to take Betolvan

Do not take a double dose to compensate for a forgotten tablet.

If you stop taking Betolvan

Treatment with vitamin B₁₂ 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 B₁₂ deficiency will eventually come back.

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

4. Possible side effects

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

Stop taking Betolvan and immediately contact a doctor if you get any of the following symptoms of 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 Betolvan:

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Betolvan

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and 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 Betolvan contains

- The active substance is cyanocobalamin (vitamin B₁₂). 1 tablet contains 1 mg cyanocobalamin.
- The other ingredients are: mannitol, potato starch, pregelatinised starch, microcrystalline cellulose, magnesium stearate, stearic acid, partially hydrolyzed polyvinyl alcohol, macrogol, talc, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

What Betolvan looks like and contents of the pack

The tablet is pink, round, biconvex with a diameter of 8 mm.

Plastic jar (safety sealed) with plastic lid and plastic seal containing 90, 100, 105 or 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in

2024-11-14