Celix Pharma

Package leaflet: Information for the patient

Cyanocobalamin 1 mg Film-coated Tablets

cyanocobalamin

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.

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1. What Cyanocobalamin Film-coated Tablets are and what they are used for

Cynocobalamin film coated tablets contains vitamin B_{12} in the form of cyanocobalamin (a synthetic form of the vitamin, which the body converts into active vitamin B_{12}).

Most people get enough vitamin B_{12} through their diet, but if you have had stomach surgery, have certain gastrointestinal disorders, are on a strict diet or if you are using certain medicines, your body may not be getting enough vitamin B_{12}.

Cynocobalamin film coated tablets is used in adults in the following situations:

- Treatment of vitamin B_{12} deficiencies due to poor nutrition
- Long-term-treatment of vitamin B_{12} deficiencies, for example due to problems with intestinal absorption
- Oral treatment of pernicious anaemia (a specific type of anaemia) and vitamin B_{12} deficiency with symptoms of the nervous system, after the vitamin B_{12} blood-level has been normalized with vitamin B_{12} injections.

Note: In case you need rapid normalization of your vitamin B_{12} blood-level, the remission initial treatment should be performed with vitamin B_{12} injections.

2. What you need to know before you take Cyanocobalamin Film-coated Tablets

Do not take Cyanocobalamin Film-coated Tablets:

- if you are allergic to cyanocobalamin or any of the other ingredients of this medicine (listed in section 6).
- if you have a specific type of anaemia called megaloblastic anaemia, that is caused solely by a lack of folic acid (vitamin B_9).
- you have a condition requiring the removal of cyanide from your body (detoxification) (e.g. in pernicious anaemia accompanied by inflammation of the optic nerve [optic neuritis]). In this situation, other vitamin B_{12} preparations must be used.
- you have vitamin B_{12} deficiency and you suffer from a specific hereditary disease of the eye (Leber's optic atrophy).
- if you have been diagnosed with poor eyesight (amblyopia) caused by tobacco or alcohol.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cyanocobalamin film coated tablets.

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 B_{12} from food and whether oral supplementation with Cyanocobalamin film coated 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 need regular kidney dialysis, your doctor should carry out regular blood tests and the dosage of Cyanocobalamin film coated tablets may need to be reduced.

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Children and adolescents

Cyanocobalamin film coated tablets are not suitable for children and adolescents under 18 years of age, as not enough clinical data are available and the dose is unsuitable.

Other medicines and Cyanocobalamin Film-coated Tablets

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

Uptake or effect of Cyanocobalamin Film-coated Tablets can be diminished by the following substances:

- proton pump inhibitors (e.g. omeprazole) and histamine H2 antagonists (e.g. cimetidine), both used to treat excess stomach acid that causes indigestion or ulcers
- colchicine, an active substance used in gout
- neomycin and chloramphenicol, which belong to the antibiotic group cholestyramine
- biguanides, e.g. metformin, used in diabetes mellitus
- aminosalicylic acid, used to treat inflammatory diseases of the digestive tract
- prolonged use of nitrous oxide (a gas used in anaesthesia)
- second-generation antipsychotic agents used in mental disorders (e.g. olanzapine and risperidone).

Uptake or effect of Cyanocobalamin Film-coated Tablets can be increased by the following substances:

- glucocorticoids, e.g. prednisone, used to treat inflammation.

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 to take Cyanocobalamin Film-coated Tablets

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

Use in adults

The usual dose is 1 film-coated tablet daily, preferably on an empty stomach.

In pernicious anaemia and conditions of the nervous system, treatment must initially be given by infusion/injection, until blood values have returned to normal.

Please take the tablet with ½ glass of water.

Use in children and adolescents
Cyanocobalamin Film-coated Tablets are not suitable for use in children and adolescents under 18 years of age.

Use in elderly patients
Elderly patients receive the same dose as adults.

If you have kidney dysfunction
Cyanocobalamin film coated tablets can be used at the normal dosage in patients with moderate kidney dysfunction.
If you have serious kidney dysfunction, your doctor may reduce the dose. Your doctor will also regularly monitor the level of vitamin B_{12} in your blood.

If you have liver dysfunction
It is not known whether it is safe to take this medicine if your liver function is impaired. Please tell your doctor if you have liver dysfunction.

If you take more Cyanocobalamin Film-coated Tablets 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 Cyanocobalamin Film-coated Tablets
Treatment with vitamin B_{12} 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 Cyanocobalamin Film-coated Tablets 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 cyanocobalamin:

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, nurse or pharmacist.
This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: http://www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cyanocobalamin Film-coated Tablets

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.

6. Contents of the pack and other information

What Cyanocobalamin Film-coated Tablets contains
- The active substance is: Cyanocobalamin 1 mg (vitamin B_{12}).
- The other excipients are: Mannitol, microcrystalline cellulose, pregelatinized starch, potato starch, stearic acid, magnesium stearate. Film-coating: Rice starch, isomalt, hypromellose (E464), medium chain triglycerides, Iron Oxide Yellow (E172), Black Iron Oxide (E172) and Carmine (E120).

What Cyanocobalamin Film-coated Tablets looks like and contents of the pack
Light pink to pink, round, biconvex, film coated tablets, 8 mm diameter, debossed with "C" on one side and plain on other side.

The tablets are available in PVC/PVDC - Alu blister pack.

Each blister pack contains 30 Film-coated Tablets.

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