

PATIENT INFORMATION LEAFLET

BEVIT-B12 film tablets

For oral use.

- **Active substance(s):** Each film tablet contains 250 mg pyridoxine hydrochloride (vitamin B6), 250 mg thiamine hydrochloride (vitamin B1) and 1 mg cyanocobalamin (vitamin B12).
- **Excipient(s):**

Tablets: Lactose monohydrate (derived from cow's milk), microcrystalline cellulose, povidone K30, talc

Coating material: Hydroxypropyl methylcellulose, copovidone, polydextrose, polyethylene glycol, medium chain triglycerides, titanium dioxide (E 171), carmoisine lacquer (E 122) and ponso 4R lacquer (E 124).

Read this PATIENT INFORMATION LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. *What BEVIT-B12 is and what it is used for?*
2. *What you need to know before you use BEVIT-B12?*
3. *How to use BEVIT-B12?*
4. *Possible side effects*
5. *How to store BEVIT-B12?*

1. What BEVIT-B12 is and what it is used for?

- BEVIT-B12 is a vitamin B complex containing 250 mg vitamin B1, 250 mg vitamin B6 and 1 mg vitamin B12 in each tablet. Each box contains 30 or 60 tablets in blister packs.
- BEVIT-B12, which is a combination of vitamins B1, B6 and B12, shows pain-relieving properties. BEVIT-B12 shows an effect far above the effect to be achieved by using these vitamins individually.

BEVIT-B12 is used in the following cases:

- In patients with risk factors for vitamin B1, B6 and B12 deficiency
- In patients with general complaints such as rapid fatigue, forgetfulness, irritability, weakness, tremor
- In nerve inflammation, nerve damage due to diabetes, nerve pain, shingles

- In other painful conditions such as arthritis, periarticular inflammation, sciatica, low back pain, joint pain, muscle pain, cramps and rheumatic pain
- As an aid in the treatment of heart muscle disorders, vomiting after surgery, radiation sickness, febrile rheumatism and intoxication, especially during alcoholism.

2. What you need to know before you use BEVIT-B12?

DO NOT use BEVIT-B12

If

- you are allergic to one of the ingredients in the medicine
- you are pregnant or breastfeeding
- you are under 12 years of age
- you have liver or kidney failure

Warnings and precautions

- If you have Parkinson's disease treated with levodopa alone, you should not take more than several times the daily vitamin B6 requirement of 2 mg.
- If you have Leber's disease (hereditary reduction in optic nerve volume)
- If you have severe megaloblastic anaemia (a type of anaemia caused by vitamin B12 and/or folic acid deficiency)

In case of decreased vitamin B12 concentration or abnormal decrease in concentration with maximum dose intake, irreversible neurological (nervous system related) damage may occur if inadequate treatment is taken for more than 3 months.

Folate deficiency; it has not been shown, but the expected favourable response may not be observed as a result of treatment.

Since it contains a high dose of pyridoxine hydrochloride (vitamin B6), the recommended dosage and duration of treatment should not be exceeded. Because if it is not taken as recommended, serious neurotoxicity (undesirable side effect occurring in the nervous system) may be observed.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

BEVIT-B12 with food and drink

Excessive alcohol intake for more than two weeks may reduce the absorption of vitamin B12 from the digestive tract.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

It should not be used during pregnancy because it contains high doses of vitamin B6 that greatly exceed the Recommended Daily Dietary Allowance. Women of childbearing potential must use effective contraception during treatment. Vitamins B1, B6 and/or B12 have no effect on hormonal contraception. However, there are no studies on other methods of contraception.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

It should not be used during breastfeeding due to the high dose of vitamin B6, which greatly exceeds the "Recommended Daily Dietary Allowance".

Driving and using machines

No effects on the ability to drive and use machines have been observed.

Important information about some of the excipients of BEVIT-B12

Since BEVIT-B12 contains lactose monohydrate, if you have been told by your doctor that you have an intolerance (intolerance) to some sugars, contact your doctor before taking this medicinal product.

As this medicinal product contains carmoizine lac (E 122) and ponso 4R lac (E 124), it may cause allergic reactions.

Other medicines and BEVIT-B12

When used with some medicines, the effect of BEVIT-B12 or the other medicine used may change. Tell this to your doctor:

- Thiosemicarbazone (a drug with antiviral, antifungal and antibacterial action)
- 5-fluorouracil (used in cancer treatment)
- Antacid (drugs used in heartburn and indigestion)
- Levodopa (used in Parkinson's disease)
- Cycloserine (antibiotic)
- Hydralazine group drugs (used in high blood pressure and heart failure)
- Isoniazid (used in the treatment of tuberculosis)
- Desoxypyridoxine
- D-penicillamine (antibiotic)
- Contraceptive pill
- Alcohol
- Aminosalicates (used in the treatment of inflammatory bowel diseases)
- Colchicine (used in rheumatic diseases), especially if used together with antibiotics called aminoglycosides
- Antibiotics
- Folic acid
- Histamine (H2) receptor antagonists (used in stomach disorders)
- Metformin (used in non-insulin-dependent diabetes)
- Proton pump inhibitors (used in stomach disorders)
- Vitamin C

Effects on assays

- Vitamin B1 may cause false positive results in the urobilinogen determination using Ehrlich's reagent.
- High doses of vitamin B1 may prevent the spectrophotometric determination of blood concentrations of theophylline, which is used in the treatment of respiratory diseases.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use BEVIT-B12?

- **Instructions for use and dosage/frequency of administration:**

Unless your doctor advises otherwise, use 1 film-coated tablet per day.

The product is usually prescribed for one to several weeks. In these cases, the doctor may extend the treatment period for a few more months.

- **Route of administration and method:**

BEVIT-B12 tablets should be swallowed whole with sufficient liquid and used in recommended doses.

- **Different age groups:**

- Use in children:**

- It should not be used in children 12 years of age or younger.

- Use in elderly:**

- No specific dosage recommendations were given.

- **Special cases of use:**

- Renal/Hepatic failure:**

- It should not be used in patients with renal and hepatic failure.

If you have impression that the effect of BEVIT-B12 is very strong or weak, tell a doctor or pharmacist.

If you use more BEVIT-B12 than you should:

There is no evidence that this product may cause an overdose if used as recommended.

Symptoms of an overdose include loss of sensation and impaired coordination of movements as a result of nerve damage, nausea, headache, numbness, drowsiness, increased blood AST levels (an enzyme test often used to diagnose heart and liver disease) and decreased blood folic acid concentrations. The effects resolve if treatment is stopped.

If you take more BEVIT-B12 than you should, tell your doctor or pharmacist.

If you forget to use BEVIT-B12:

Do not take a double dose to make up for a forgotten dose.

If you stop using BEVIT-B12:

There are no known effects.

4. Possible side effects?

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

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

If you notice any of the followings stop taking BEVIT-B12 and immediately inform your doctor or go to the nearest emergency department:

Allergic reactions;

- Redness and water-filled blisters (hives)
- Rashes
- Swelling on the face
- Difficulty breathing with wheezing
- Skin blisters

All of these are very serious side effects of unknown frequency. If you have any of these, you are seriously allergic to BEVIT-B12. You may need urgent medical attention or hospitalisation.

If you notice any of the followings immediately inform your doctor or go to the nearest emergency department:

- Dizziness
- Headache
- Peripheral neuropathy (conditions that occur when the nerves that connect to the brain and spinal cord from other parts of the body are damaged or diseased)
- Somnolence (not too deep semi-conscious sleepy state or a tendency to sleep)
- Paresthesia (sensory disturbance in the perception of touch, pain, temperature or vibration stimuli)
- Increased aspartate aminotransferase (increased levels of the enzyme aspartate aminotransferase (ASP-SGOT) following tissue damage in the liver, heart, muscle tissue, kidney or brain)
- Decreased blood folate levels (decreased levels of folate, a water-soluble B vitamin, in blood serum in cases of high cell division rate such as alcoholism, pregnancy, anaemia, cancer or inadequate dietary intake)

These are all serious side effects of unknown frequency. Emergency medical intervention may be required.

If you notice any of the following, tell your doctor:

- Diarrhoea
- Indigestion
- Nausea
- Abdominal pain
- Abnormal urine odour

These are mild side effects of BEVIT-B12 of unknown frequency.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

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 clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. 5. How to store BEVIT-B12?

Keep this medicine out of the sight and reach of children in its original packaging.

Store at room temperature below 25°C and in a dry place.

Use in accordance with expiry date.

Do not use this medicine after the expiry date which is stated on the package.

Do not use BEVIT-B12 if you notice any defects in the product and/or its packaging.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

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This patient information leaflet was last approved on../../.....