

Package leaflet: Information for the user

Bevitrio 0.5 mg/0.8 mg/3 mg tablets

cyanocobalamin (vitamin B₁₂)/folic acid/pyridoxine hydrochloride (vitamin B₆)

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What [invented name] is and what it is used for

[Invented name] contains three B vitamins (folic acid, vitamin B₁₂ and vitamin B₆). B vitamins are important in maintaining the natural functions of the cells. [Invented name] should be used for the prevention of symptom-causing deficiency of vitamin B₆, vitamin B₁₂ and folic acid caused by insufficient food intake or poor uptake of nutrients, particularly in the elderly.

2. What you need to know before you take [invented name]

Do not take [invented name]

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking [invented name].

[Invented name] should not be used by patients who have had large parts of the small intestine removed by surgery.

[Invented name] should not be used for preventive use if you have given birth to a child with neural tube defects, since higher doses of folic acid than present in this medicine is needed.

Other medicines and [invented name]

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

The effect of treatment may be influenced if this medicine is taken with certain other medicines, for instance:

- phenobarbital and phenytoin (medicines for epilepsy)
- some antibiotics used in the treatment of bacterial infections

- methotrexate, pyrimethamine, trimetoprim, sulfonamides and sulfasalazine, since they reduce the effect of folic acid
- levodopa (medicine for Parkinson's disease)
- aminoglycosides (for serious infections)
- aminosalicic acid (for chronic, bleeding inflammation in the bowel)
- metformin (for diabetes)
- chloramphenicol (for infection in the eye)
- cholestyramine (for high cholesterol)
- potassium salts (for lack of potassium)
- omeprazole and cimetidine (medicines for excessive stomach acid).

Your doctor should therefore be informed if you are receiving any of these medicines at the same time.

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.

[Invented name] can be used during pregnancy and breast-feeding.

Driving and using machines

[Invented name] is not expected to affect your reaction time, for instance when driving or working with precision machinery.

[Invented name] contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take [invented name]

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

Your doctor will choose the dose which suits you best.

The recommended dose is 1 tablet daily. The tablet should be swallowed whole with water.

If you take more [invented name] than you should

If you have taken more [invented name] than you should, or if children have been taking the medicine by accident, please contact your doctor or hospital to get an opinion of the risk and advise on action to be taken.

If you forget to take [invented name]

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

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. At the recommended dosage the risk of side effects is low.

Not known: frequency cannot be estimated from the available data

- Acne-like rash. Allergic skin reactions such as hives, itching and redness.
- Severe allergic reaction (anaphylactic reaction).

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 [invented name]

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

Do not store above 30°C.

Store in the original container in order to protect from light.

Do not use this medicine after the expiry date which is stated on the bottle. 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 [invented name] contains

- The active substances are 0.5 mg cyanocobalamin (vitamin B₁₂), 0.8 mg folic acid and 3 mg pyridoxine hydrochloride (vitamin B₆).
- The other ingredients are cellulose, microcrystalline (E 460); calcium hydrogen phosphate dihydrate; sodium starch glycolate (type A); silica, colloidal anhydrous (E 551) and magnesium stearate (E 470b).

What [invented name] looks like and contents of the pack

[Invented name] is a red/yellow round and biconvex tablet, mottled with small red spots. The diameter of the tablet is 10 mm.

White plastic bottle with a white plastic screw cap.

Pack sizes: 100 and 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in

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Detailed information on this medicine is available on the web site of {MA/Agency}.