

Package leaflet: Information for the user

TrioBe tablet

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

Read all of this 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, 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.

What is in this leaflet:

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

1. What TrioBe is and what it is used for

TrioBe contains three B vitamins (folic acid, vitamin B₁₂ and vitamin B₆). B vitamins are important in maintaining the natural functions of the cells. TrioBe 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 use TrioBe

Do not use TrioBe

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).
- For preventive use if you have given birth to a child with neural tube defects, since higher doses of folic acid than present in TrioBe is needed.

Warnings and precautions

Talk to your doctor or pharmacist before taking TrioBe.

TrioBe is not intended for the treatment of symptom-causing deficiency of the vitamins included. Effective treatment of some types of anaemia (lack of red blood cells) may require treatment with vitamin B₁₂ injections.

TrioBe should not be used by patients who have had large parts of the small intestine removed by surgery.

Other medicines and TrioBe

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because certain medicines may affect or be affected by treatment with TrioBe.

Tell your doctor if you are using any of the following:

- Phenytoin or phenobarbital used to treat epilepsy
- Methotrexate used to treat cancer and autoimmune diseases
- Trimetoprim used for treatment of bladder infections
- Pyrimethamine used to treat parasitic diseases like toxoplasmosis
- Altrexamine used to treat cancer
- Levodopa used to treat Parkinson's disease
- Colchicine used as anti-inflammatory medicine, e.g. to treat gout
- Para-aminosalicylic acid used as antibiotic for tuberculosis
- Omeprazole used to treat acid reflux and stomach ulcers

TrioBe with alcohol

You should not drink a lot of alcohol or drink alcohol frequently during your treatment with TrioBe, as alcohol reduces the uptake of vitamin B₁₂ (one of the active substances of TrioBe).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will decide if you should use TrioBe during pregnancy. There are no known risks of TrioBe during pregnancy with normal doses. The recommended daily dose should not be exceeded.

TrioBe can be used during breast-feeding. No effects are anticipated on the breast-fed newborn/infant at normal doses.

Driving and using machines

TrioBe is not expected to affect your reaction time, for instance when driving or working with precision machinery.

TrioBe 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 TrioBe

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 dosage is one tablet daily. The tablet can be chewed or swallowed whole.

If you take more TrioBe than you should

If you have taken more TrioBe than you should, or if children have been taking 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 TrioBe

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

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.

Rare (occur in less than 1 in 1000 patients): Acne-like rash. Allergic skin reactions such as hives, itching and redness.

Not known (cannot be estimated from the available data): Severe allergic reaction (anaphylactic reaction).

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell 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 the national reporting system (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store TrioBe

Keep out of the sight and reach of children.

Do not store above 30° C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the package. 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. The measures will help protect the environment.

6. Contents of the pack and other information

What TrioBe contains

- The active substances are 0.5 mg vitamin B₁₂, 0.8 mg folic acid, and 3 mg vitamin B₆.
- The other ingredients are calcium hydrogen phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, colloidal anhydrous silica.

What TrioBe looks like and contents of the pack

TrioBe tablet is a round, pale yellow, speckled tablet with a diameter of 10 mm.

Pack sizes: 60, 100 and 250 tablets in plastic bottles with screw-on lids.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<< *To be completed locally* >>

Manufacturer

Mylan Laboratories SAS

Route de Belleville

01400 Châtillon-sur-Chalaronne

France

This medicinal product is authorised in the Member States of the EEA under the following names:

TrioBe (Denmark, Finland, Norway and Sweden).

TriBvit (Belgium).

This leaflet was last revised on 2023-09-15.