

PACKAGE LEAFLET: INFORMATION FOR THE USER

B-COMPLEX

25 mg +20 mg + 5 mg + 5mg + 2 mg + 4 mg + 1 mcg, coated tablet

B-COMPLEX VITAMINS

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What B-COMPLEX is and what it is used for
2. Before you take B-COMPLEX
3. How to take B-COMPLEX
4. Possible side effects
5. How to store B-COMPLEX
6. Further information

1. WHAT B-COMPLEX IS AND WHAT IS IT USED FOR

B-COMPLEX contains B vitamins, which stimulate the metabolism of carbohydrates, fats and proteins.
ATC code: A11EA.

The lack of one of these vitamins or increased need for them can cause the need for other vitamins from this group. Therefore, when there is evidence of the lack of any vitamin B, it is necessary to take the whole complex of vitamin B.

B-COMPLEX is used:

- For the prevention and treatment of hypovitaminosis B and avitaminosis B,
- In conditions with increased need for vitamins B,
- For impaired absorption of vitamins in patients with diseases of the digestive system and the liver,
- If you have beriberi, neuralgia, polyneuritis, neurodermatoses.

2. BEFORE YOU TAKE B-COMPLEX

Do not use B-COMPLEX

- If you are allergic (hypersensitive) to any other ingredient of this medicine.

- If you have hypervitaminosis of certain vitamins.

Take special care with B-COMPLEX

During administration of B-COMPLEX the urine may become yellow due to higher content of riboflavin. Hypersensitivity reactions are extremely possible.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

Simultaneous administration of B-COMPLEX and levodopa can reduce the effect of levodopa (due to pyridoxine).

Longer-term use of antimicrobial agents that change the intestinal flora and the absorption, causes secondary deficiency of vitamins from group B.

Pregnancy and breast-feeding

Pregnant and breastfeeding women can take B-COMPLEX tablets at the recommended doses.

Driving and using machines

B-COMPLEX should not affect your ability to drive and use machines.

Other warnings

This medicine contains lactose and sucrose. In case of intolerance to some sugars, contact your doctor before using this medicine.

Azo dyes tartrazine (E102), orange yellow (E110) and black PN (E151) may cause allergic-type reactions.

3. HOW TO TAKE B-COMPLEX

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage and administration

Adults: 1 to 2 coated tablets 2 to 3 times a day.

Children 5-14 years: 1 coated tablet per day.

The whole coated tablet should be swallowed with fluid.

If you feel that the effect of the medicine is too strong or too weak, talk to your doctor or pharmacist.

If you take more B-COMPLEX than you should

If you have taken more medicine than you should, talk to your doctor or pharmacist.

Prolonged use of doses much higher than recommended can cause headaches, irritability, insomnia, chills and diarrhea.

If you forget to take B-COMPLEX

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

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, B-COMPLEX can cause side effects, although not everybody gets them.

If B-COMPLEX is taken in recommended doses, side effects are rare and mild.

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100
Uncommon: 1 to 10 treated persons of 1000
Rare: 1 to 10 treated persons of 10000
Very rare: less than 1 treated person of 10000
Not known: frequency cannot be estimated from the available data

Very rare side effects (occurring in less than 1 in 10,000 patients):

Hypersensitivity reactions (allergy), headache, blurred vision, dizziness, diarrhea, vomiting, nausea or skin inflammation.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE B-COMPLEX

Keep out of the reach and sight of children.

Do not store above 25 °C, in the original package, protected from moisture.

Do not use B-COMPLEX after the expiry date which is stated on the label.
Shelf life: 2 years.

6. FURTHER INFORMATION

What B-COMPLEX contains

The active substances are vitamins of the B complex. One coated tablet contains 4 mg of tiaminhlorida (Thiaminum), 5 mg of riboflavin (Riboflavinum), 2 mg of piridoksinhlorida (Pyridoxinum), 1 mcg of cyanocobalamin (Cyanocobalaminum), 5 mg of calcium pantothenate (Calcii pantothenas), 25 mg of nicotinamide (Nicotinamidum), 20 mg of 4-aminobenzoic acid (Acidum 4-aminobenzoicum).

- The other ingredients in the tablet core are povidone, lactose monohydrate, maize starch, talc (E553b), magnesium stearate (E572). The other ingredients in the film coating are: sucrose, talc (E553b), calcium carbonate (E170), gum arabic (E414), tartrazine (E102), orange yellow (E110), black PN (E151), iron oxide (E172) and macrogol 6000

What B-COMPLEX looks like and contents of the pack

The tablets are round, biconvex, chocolate brown in color.

B-COMPLEX is also available in the blister of 15 coated tablets; each box contains a total of 30 or 60 coated tablets.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

KRKA, tovarna zdravil, d.d., Šmarješka cesta 6, Novo mesto, Slovenia