

PACKAGE LEAFLET: Information for the patient

VITAMINE B KOMPLEKS

Sugar-coated tablets – (5 mg / 2 mg / 2 mg / 30 mg)

(Thiamine hydrochloride, Pyridoxine hydrochloride, Riboflavin, Nicotinamide)

Read this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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4. Possible side effects
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1. WHAT VITAMINE B KOMPLEKS IS AND WHAT IT IS USED FOR

Vitamine B Kompleks sugar-coated tablet takes part in the metabolism of carbohydrates, fats and proteins. Deficiency of any of these vitamins or the increase of demand for them, causes a bigger demand for all the vitamins of this group.

Vitamine B Kompleks sugar-coated tablets are used in:

- the prophylaxis and treatment of hypovitaminosis B and of avitaminosis;
- the increased demand for vitamins of the B complex (e.g. the growth and development of children, pregnancy period and breastfeeding);

- vitamin absorption disorders in several diseases of the gastrointestinal tract and in liver diseases;
- beriberi;
- neuralgia;
- polyneuritis;
- neurodermatosis.

2. BEFORE YOU TAKE VITAMINE B KOMPLEKS

Do not take Vitamine B Kompleks and ask your doctor if:

- you have a known hypersensitivity to the complex of the B vitamins or to the excipients of the sugar-coated tablets;
- you have hypervitaminosis of specific vitamins.

Take special care with Vitamine B Kompleks

Consult with your doctor or pharmacist before taking Vitamine B Kompleks. During the use of Vitamine B Kompleks, urine may take an orange or bright yellow colour because of the presence of riboflavin.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Vitamine B Kompleks. Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Vitamine B Kompleks if you have been given any other drug during treatment, because the concomitant treatment of Vitamine B Kompleks and levodopa may cause the decrease of the effect of the latter (because of pyridoxine).

Pregnancy and breastfeeding

Ask for the advice of the doctor or pharmacist before taking this drug.

Pregnancy

Risk in pregnancy: Category C.

There are not yet performed studies in pregnancy, in humans or animals. It is recommended to be taken only when the benefits for the mother outweigh the risks for the foetus.

Breastfeeding

Some ingredients of Vitamine B kompleks are excreted through breast milk. Follow the recommendation of the doctor if you have to take Vitamine B kompleks during breastfeeding.

Driving and using machinery

Vitamine B Kompleks does not affect the ability to drive and use machinery. For this reason, it can be taken without any problem by patients.

Important information about some of the excipients of Vitamine B Kompleks

This drug contains lactose and sucrose. If you have an intolerance to some sugars, contact your doctor before taking this drug.

Vitamine B Kompleks contains the azodye Sunset yellow FCF (E 110), which may cause allergic reactions.

Vitamine B Kompleks contains sodium benzoate.

3. HOW TO TAKE VITAMINE B KOMPLEKS

Always take Vitamine B Kompleks as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Vitamine B Kompleks are too strong or too weak, talk to your doctor or pharmacist.

The sugar-coated tablets should be taken by mouth with at least a glass of water (250 ml of water).

It is advised not to take alcoholic drinks during the time you are taking this drug.

Dosage:

Adults: 1 - 2 sugar - coated tablets, 2 - 3 times daily.

Children from 5 to 14 years old: 1 sugar - coated tablet, once daily.

If you have taken more Vitamine B Kompleks

There are no data on the overdose from Vitamine B Kompleks.

If you have taken more Vitamine B Kompleks than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Vitamine B Kompleks

If you forget a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Vitamine B Kompleks may cause side effects, although not everybody manifests them.

Vitamine B Kompleks side effects appear in very rare cases and in sensitive people. In these people hypersensitivity reactions may occur.

During the treatment with Vitamine B Kompleks urine may take an orange or bright yellow colour (because of riboflavin).

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE VITAMINE B KOMPLEKS

Keep out of the reach and sight of children!

Do not use Vitamine B Kompleks after the expiry date which is stated on the package.

Store below 25°C.

Store in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION

What Vitamine B Kompleks contains

The active substances are: thiamine hydrochloride, pyridoxine hydrochloride, riboflavin and nicotinamide.

Each sugar-coated tablet contains 5 mg thiamine hydrochloride, 2 mg pyridoxine hydrochloride, 2 mg riboflavin and 30 mg nicotinamide.

The excipients are: calcium pantothenate, microcrystalline cellulose, lactose, povidone, magnesium stearate, sodium starch glycolate, talc, gelatin, calcium carbonate, titanium dioxide, sucrose, yellow iron oxide, red iron oxide, Sunset yellow FCF (E 110), sodium benzoate, shellac, carnauba wax, beeswax white.

Content of the pack:

Carton box with 30 sugar-coated tablets and carton box with 60 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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