

PACKAGE LEAFLET: INFORMATION FOR THE USER

Plibex

Film-coated tablets

• 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 PLIBEX is and what it is used for
2. Before you take PLIBEX
3. How to take PLIBEX
4. Possible side effects
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1. WHAT PLIBEX IS AND WHAT IT IS USED FOR

Plibex film-coated tablets are vitamin preparation containing B vitamins, and are used for the prevention or treatment of conditions when there is a lack or deficiency of vitamin B (avitaminosis or hypovitaminosis).

Prevention of hypovitaminosis

- In conditions with increased need for vitamins B
- Due to insufficient intake of vitamin B (parenteral nutrition, diet, loss of appetite)
- Due to impaired absorption and utilization of vitamin B (vomiting, diarrhea, inflammation of the digestive system (gastritis, enteritis), sprue, stomach resection, liver disease)
- Due to medical treatment with some medicines (antibacterial drugs, chemotherapeutic agents, cytostatics, anticonvulsants, oral contraceptives)

Treatment of hypovitaminosis and avitaminosis in the following conditions:

- Beriberi, ariboflavinosis, pellagra;
- Diseases of the skin;
- Inflammation of the nerves (neuritis, neuralgia, polyneuritis);

- Vitamin deficiency in chronic alcoholics.

2. BEFORE YOU TAKE PLIBEX

Do not take PLIBEX

- If you are allergic (hypersensitive) to one of the active substances or any other ingredient of this medicine.

Take special care with PLIBEX if you

- are taking medicine levodopa to treat Parkinson's disease simultaneously as taking Plibex film-coated tablets may reduce the effect of the medicine;
- drink alcohol;
- are taking immunosuppressants, cycloserine, isoniazid, penicillamine, ethionamide, hydralazine and oral contraceptives because the need for vitamins B can be increased;
- are taking neomycin, colchicine, para-aminosalicylic acid, cimetidine, potassium preparations or chloramphenicol because they can interfere with the effectiveness of Plibex film-coated tablets.

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.

Pregnancy and breast-feeding

Pregnant and breastfeeding women can take Plibex tablets at the recommended doses.

Driving and using machines

PLIBEX should not affect your ability to drive and use machines.

Other warnings

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

3. HOW TO TAKE PLIBEX

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.

Plibex film-coated tablets should be swallowed whole with fluid.

For the prevention of hypovitaminosis (lack of vitamin B) you should take 1 tablet per day, and for the treatment, 1 to 2 tablets 2 to 3 times a day.

These doses may not be exceeded.

If you take more PLIBEX than you should

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

You may experience disturbances in the digestive system, but taking high doses over a prolonged period of time can cause rare disorders of the nervous system.

If you forget to take PLIBEX

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, PLIBEX can cause side effects, although not everybody gets them.

Side effects of Plibex film-coated tablets are very rare. Hypersensitivity reaction to any ingredient of the medicine and redness may occur.

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 PLIBEX

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use PLIBEX after the expiry date which is stated on the label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What PLIBEX contains

The active substances are B vitamins.

One Plibex film-coated tablet contains: 25 mg of nicotinamide, 5 mg of tiaminklorida, 5 mg of riboflavin, 5 mg of calcium pantothenate, 2 mg of pyridoxine chloride, 1 microgram of cyanocobalamin.

Plibex film-coated tablets also contain the following inactive ingredients: lactose; povidone; gelatin; corn starch; talc; magnesium stearate; hypromellose; macrogol 6000 and the color erythrosine (E 127) and iron oxide yellow (E 172).

What PLIBEX looks like and contents of the pack

Plibex film-coated tablet is red, round, biconvex film-coated tablet.

The core of the film-coated tablets is yellow-orange in color.

Plibex film-coated tablets are available in packs of 30 or 60 film-coated tablets in blister, in a box.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

PLIVA CROATIA, Ltd.

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