

PACKAGE LEAFLET: INFORMATION FOR THE USER

Plivit C

50 mg tablets

ASCORBIC ACID

• 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 PLIVIT C is and what it is used for
2. Before you take PLIVIT C
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1. WHAT PLIVIT C IS AND WHAT IT IS USED FOR

Plivit C tablets contain ascorbic acid (vitamin C). Vitamin C is a water soluble vitamin, and in organism it is a part of various metabolic processes. It has a significant role in the construction of different tissues (skin, bones, teeth, cartilage, tendons, blood vessels), and it is entered through food because the human body is unable to synthesize it.

Plivit C tablets are used for the prevention and treatment of scurvy and lack of vitamin C in the body (hypovitaminosis).

2. BEFORE YOU TAKE PLIVIT C

Do not take PLIVIT C

- If you are allergic (hypersensitive) to the active substance, ascorbic acid, or any other ingredient of this medicine.
- If you have kidney stones.

Take special care with PLIVIT C

- if you have kidney stones
- if you have a deficiency of glucose-6-phosphate dehydrogenase deficiency (an inherited metabolic disorder of red blood cells)
- if you have hemochromatosis (a disorder of iron metabolism that is reflected in the increased disposal of iron), sideroblastic anemia, thalassemia (hereditary disorder of structure of hemoglobin)
- if you have diabetes

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.

Before you take Plivit C tablets, tell your doctor if you are taking any of the following medications:

- Iron - Vitamin C may increase its absorption
- deferoxamine (a medicine used to remove excess iron from the body)
- sulfonamides (antibiotics or drugs for the treatment of bacterial infections)
- warfarin (a medicine that prevents blood clotting) - Vitamin C may reduce its activity
- oral contraceptives (contraceptive medication) - vitamin C increases the serum level of estrogen which leads to undesirable effects
- bortezomid (medication to treat multiple myeloma) - Vitamin C may reduce the therapeutic effect of bortezomida
- cyclosporine (a medicine used after organ transplantation and in some severe forms of the disease such as psoriasis, arthritis, etc.) - Vitamin C may reduce levels of cyclosporine

Smoking lowers levels of ascorbate acid (vitamin C), the active substance of Plivit C tablet in your blood.

Ascorbic acid (vitamin C) may affect the results of some laboratory tests (eg. Glucose in the urine, liver blood tests, the determination of bilirubin, iron, and ferritin levels, the determination of pH of urine, uric acid, and the oxalate, the determination of blood in the stool). Therefore, because of all of the above mentioned, stop taking Plivit C tablets 48-72 hours prior to these examinations.

Pregnancy and breast-feeding

Consult your doctor or pharmacist before taking any medicine.

- The daily requirement of vitamin C during pregnancy and breastfeeding should be to satisfy the proper and varied diet.
- Pregnant and breastfeeding women should not take doses of ascorbate acid that are higher than recommended daily doses due to potential risk of harmful consequences.

Driving and using machines

PLIVIT C should not affect your ability to drive and use machines.

3. HOW TO TAKE PLIVIT C

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.

For the prevention of hypovitaminosis C in children the recommended dose is 1 to 2 tablets of 50 mg once daily.

The dose for the prevention and treatment of scurvy in children is 1 to 2 tablets of 50 mg three times daily for at least 2 weeks.

For the prevention of hypovitaminosis C in adults the recommended dosage is 200 to 500 mg once daily.

The tablets should be swallowed whole with a glass of water.

For the treatment of scurvy in adults Plivit C tablets of 500 mg are used.

If you take more PLIVIT C than you should

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

If you forget to take PLIVIT C

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.

If you stop taking Plivit C tablets

The only possible consequence if you stop taking Plivit C tablets is that the symptoms that caused you to take them occur again.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, PLIVIT C can cause side effects, although not everybody gets them.

Ascorbic acid (vitamin C) is usually well tolerated.

Side effects usually occur after prolonged administration of high doses (oral doses higher than 1 g per day can cause diarrhea, a dose higher than 600 mg may act mild diuretic).

Longer-term use of high doses of ascorbate acid can also cause nausea, vomiting, heartburn, stomach cramps, skin redness, headache and insomnia, and rarely hyperoxaluria (high levels of oxalate in the urine), with the possibility of the occurrence of renal oxalate stones.

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 PLIVIT C

Keep out of the reach and sight of children.

Do not store above 25 °C.

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

6. FURTHER INFORMATION

What PLIVIT C contains

The active substance in tablets Plivit C is ascorbic acid.

One Plivit C 50 mg tablet contains 50 mg of ascorbate acid.

Plivit C 50 mg tablets contain the following excipients: corn starch, talc, povidone and magnesium stearate.

What PLIVIT C looks like and contents of the pack

Plivit C 50 mg tablets are white to light yellow round tablets with beveled edges.

Plivit C 50 mg tablets are available in packs of 30 (3 x 10) tablets in blisters.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

PLIVA CROATIA, Ltd.

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