

PACKAGE LEAFLET: Information for the patient

VITAMINE C

Tablets – 100 mg

Solution for injection – 100 mg / 2 ml

(Ascorbic acid)

Read all of 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 symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

Vitamin C is a water-soluble vitamin, essential for the synthesis of collagen and intercellular material.

Vitamine C is indicated in:

- prevention and treatment of scurvy;
- prevention and treatment of situations that require a large amount of vitamin C such as: pregnancy and breastfeeding, hyperthyroidism, moderate or severe infections, bleeding from the gums, methemoglobinemia, wounds healing;

- urine acidification.

Your doctor may have given Vitamine C for a different purpose. Ask your doctor if you want to know why you have been given Vitamine C.

2. BEFORE YOU TAKE VITAMINE C

Do not take Vitamine C if:

- you are allergic to ascorbic acid or to any of the other ingredients of the formula;
- you suffer from hyperoxaluria.

Take special care with Vitamine C

Ask your doctor before you take Vitamine C if:

- you have been treated with ascorbic acid over a prolonged period because it may result in an increase of the drug metabolism (“systemic circumstances”) and deficiency may result when the intake of vitamin C is reduced to normal quantities;
- you have a genetic predisposition to haemochromatosis because in this case there may be an increased risk for greater absorption of iron. It can be added that the strong prooxidative nature of the iron-ascorbate complex exacerbates the effects related to the consumption of supplements of vitamin C from individuals who have large deposits of iron, which can contribute to oxidative damage in vivo. Ascorbic acid obtained from the diet can increase the intestinal absorption of nonhemic iron;
- you have neonates who suffer from glucose-6-phosphate dehydrogenase deficiency because there is a risk of hemolysis.

Taking large doses of the vitamin during pregnancy has resulted in neonates who suffer from scurvy.

Taking other medicines

Concomitant treatment with other medicines can affect or be affected by Vitamine C. Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Remember to inform your doctor for the

treatment with Vitamine C if you get any other drug during treatment. Be careful when you take Vitamine C along with:

- 30 mg of iron, because vitamin C increases the absorption of iron from the gastro-intestinal tract;
- aspirin, because increased urinary excretion of ascorbic acid and reduced excretion of aspirin is observed;
- salicylates, because the latter inhibit ascorbic acid capturing from leukocytes and blood platelets (thrombocytes), therefore the plasma concentration of ascorbic acid increases;
- warfarin, because its anticoagulant effect is reduced;
- fluphenazine, since its simultaneous intake leads to a decrease in plasma concentration of this drug;
- deferiprone, desferrioxamine (ascorbic acid is predicted to increase the risk of cardiovascular side effects).

In patients with normal cardiac function, Vitamine C should be introduced 1 month after starting desferrioxamine.

Regarding Vitamine C use for acidification of urine, it has been observed that acidification of urine can change the excretion of other drugs.

Taking Vitamine C with food and drinks

No data available.

Pregnancy and breastfeeding

Vitamine C can be safely administered to pregnant women or those who still breastfeed their baby, if the doses recommended by the doctor are used.

This drug crosses the placenta.

Ascorbic acid concentration in breast milk is 30 - 55 mg/l. If the recommended doses of Vitamine C are used, breastfeeding can continue during treatment with this medicine.

Driving and using machines

No data available.

Important information about some of the ingredients of Vitamine C

Vitamine C 100 mg tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before you take this medicinal product.

Vitamine C solution for injection contains sodium metabisulfite, which may rarely cause severe hypersensitivity reactions and bronchospasms.

3. HOW TO TAKE VITAMINE C

Always take Vitamine C exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

If you feel that the effects of Vitamine C are too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed with a glass of water (200 - 250 ml).

Posology is as follows:

To *prevent* deficiency the recommended dose is 25 - 75 mg per day, while to *treat* vitamin C deficiency, 250 mg or more per day is recommended.

The usual dose is:

By mouth. *Adults*: 300 - 500 mg, 2-3 times daily.

Children: 50 - 100 mg, 2-3 times daily.

With *subcutaneous, intramuscular or intravenous injection*: 150 - 300 mg which may rise up to 500 mg per day, depending on the pathology.

If you take more Vitamine C than you should

If you take more Vitamine C than you should, or if the children have taken this drug accidentally, please contact your doctor, the hospital or the nearest medical care site to take an opinion on the risk and advice on the action to be taken.

After long-term treatment with high doses of vitamin C (10 g per day), its main metabolite, oxalate, can cause the formation of kidney stones. Very high doses of vitamin C can lead to

water-electrolytic imbalance, increased destruction of red blood cells and inhibition of cobalamine activity. Moreover, high doses of vitamin C can interfere with anticoagulants and can inhibit the excretion of certain drugs administered simultaneously with it.

If you forget to take Vitamine C

If you forget to take a dose (or more), take your next dose in its usual time.

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

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

Vitamin C is well tolerated at the recommended doses.

Tell your doctor if you notice any of the following side effects:

- gastrointestinal disturbances such as: diarrhea;
- hyperoxaluria and the formation of renal calculi, as a result of precipitation of calcium oxalates;
- drug tolerance as a result of its prolonged use;
- haemolysis if you suffer from glucose 6-phosphate dehydrogenase deficiency;
- diuretic effect (increased urine flow).

Because ascorbic acid is a powerful reducing agent, it interferes with laboratory tests involving reactions of oxidation and reduction. False-negative results of plasma, faecal or urine samples tests may happen, which depend on factors such as the dose of ascorbic acid and the specific methods used.

If any of the side effects worsens, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist. If any of the above side effects occurs, the treatment with vitamin C should be stopped and you should consult your doctor or pharmacist.

5. HOW TO STORE VITAMINE C

Keep out of the reach and sight of children!

Do not use Vitamine C after the expiry date stated on the package.

Do not store above 25°C!

Keep in the original packaging to protect it from light and humidity!

6. FURTHER INFORMATION

What Vitamine C 100 mg tablets contain

The active substance is ascorbic acid.

Each tablet contains 100 mg of ascorbic acid.

Other ingredients: tartaric acid, lactose monohydrate, microcrystalline cellulose, stearic acid, talc, sodium starch glycolate, hydroxypropyl methylcellulose.

What Vitamine C solution for injections contains

The active substance is ascorbic acid.

Each 2 ml ampoule contains 100 mg ascorbic acid.

Other ingredients: sodium metabisulphite, sodium bicarbonate, water for injection.

Content of the pack

Tablets 100 mg: box with 60 tablets.

Solution for injection: box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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