

## **PACKAGE LEAFLET: Information for the patient**

### **VINAS-C**

Solution for injection – 500 mg / 5 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 only. 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 Vinas-C is and what it is used for
2. Before you take Vinas-C
3. How to take Vinas-C
4. Possible side effects
5. How to store Vinas-C
6. Further information

#### **1. WHAT VINAS-C IS AND WHAT IT IS USED FOR**

Vinas-C contains the active substance vitamin C (ascorbic acid), which is a water-soluble vitamin, essential for the synthesis of collagen and intercellular material.

Vinas-C is indicated in: prevention and treatment of scurvy, treatment of situations that require a large amount of ascorbic acid, cases of severe deficiency of ascorbic acid or in cases when taking tablets is difficult.

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

## **2. BEFORE YOU TAKE VINAS-C**

### **Do not take Vinas-C if:**

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

### **Take special care with Vinas-C**

Ask your doctor before you take Vinas-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 scurvy 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;
- you have glucose-6-phosphate dehydrogenase deficiency, because there is a risk of hemolysis;
- you suffer from renal failure, due to the risk of kidney stones formation;
- you are diabetic and are being treated with high doses of vitamin C, because you may obtain false readings of urinary glucose test.

The doctor should avoid too rapid intravenous injection.

### **Taking other medicines**

Concomitant treatment with other medicines can affect or be affected by Vinas-C. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Vinas-C if you receive any other medicine during treatment.

Be careful when you take Vinas-C along with:

- 30 mg iron, because vitamin C increases the absorption of iron from the gastro-intestinal tract;
- aspirin or other salicylates;
- warfarin, because its anticoagulant effect is reduced;
- fluphenazine, since its simultaneous intake leads to a decrease in plasma concentration of this drug;

- deferiprone, desferrioxamine, because concomitant treatment may worsen iron toxicity; also ascorbic acid is predicted to increase the risk of cardiovascular side effects; in patients with normal cardiac function, Vinas-C should be introduced 1 month after starting desferrioxamine;
- oral contraceptives which contain oestrogen, fenfluramine (appetite suppressant), phenytoin, tetracycline, because they induce tissue desaturation of ascorbic acid; also ascorbic acid is predicted to increase the risk of cardiovascular side effects;
- aluminium antacids, because a marked rise in blood aluminium levels develops which can lead to a potentially fatal encephalopathy in patients with renal failure.

### **Taking Vinas-C with food and drinks**

Do not consume alcohol and cigarettes while you are taking Vinas-C.

### **Pregnancy and breastfeeding**

Consult your doctor if you are pregnant, you are planning to have a baby or you are breastfeeding.

This drug crosses the placenta.

Ascorbic acid in doses higher than 1 g daily should not be taken during pregnancy since the effect of high doses on the fetus is unknown.

Ascorbic acid is excreted into the breast milk but there is no evidence of any hazard to the baby.

### **Important information about some of the excipients of Vinas-C**

Vinas-C solution for injection contains:

- sodium metabisulfite, which may rarely cause severe hypersensitivity reactions and bronchospasms;
- about 75.7 mg sodium (main component of cooking/table salt) in each 5 ml ampule, equivalent to about 3.8% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. HOW TO TAKE VINAS-C**

Vinas-C solution for injection is administered by a doctor.

The doctor will decide the appropriate dose for you.

Adults: 0.5 g to 1 g daily for scurvy, 200 mg to 500 mg daily for preventative therapy.

Children: 100 mg to 300 mg daily for curative purposes, or 30 mg daily for protective treatment.

Elderly: no special dosage requirements have been suggested.

#### **If you take more Vinas-C than you should**

This drug will be administered to you in a hospital, therefore there is not much possibility to occur any overdose, although you should immediately inform your doctor if you think you have taken a higher dose.

High doses may cause diarrhea and formation of renal calculi if the urine is acidic. High doses of ascorbic acid may cause the urine to become acidic causing the alteration of excretion of other drugs. Doses of 600 mg or more daily may lead to more frequent passing water.

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, Vinas-C can cause side effects, although not everybody gets them. Vinas-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;
- increased urination;
- drug tolerance as a result of its prolonged use;
- haemolysis if you suffer from glucose-6-phosphate dehydrogenase deficiency;
- transient mild soreness may occur at the site of injection; too rapid intravenous administration of the solution may cause temporary faintness or dizziness.

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 above side effects occurs, the treatment with Vinas-C should be stopped and you should consult your doctor for further treatment.

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

## **5. HOW TO STORE VINAS-C**

Keep out of the reach and sight of children!

Do not use Vinas-C after the expiry date which is stated on the packaging.

Do not store above 25°C!

Keep in the original packaging to protect it from light!

## **6. FURTHER INFORMATION**

### **What Vinas-C solution for injection contains**

**The active substance** is ascorbic acid.

Each 5 ml ampoule contains 500 mg ascorbic acid.

**The excipients are:** sodium metabisulfite, sodium bicarbonate, disodium – EDTA, water for injection.

### **Content of the pack**

Box with 10 ampoules.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

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Tirana, Albania.

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**This leaflet was last revised in January 2024.**