

LEAFLET: INFORMATION FOR THE USER

Vitamin C Arena 750 mg solution for injection Ascorbic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You might need to read it again.
- If you have any further questions, ask your physician or pharmacist.
- This medicine was prescribed for you. You do not have to give it to others. It can harm them, even if they have the same symptoms 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 you will find:

1. What is Vitamin C Arena and what it is used for
2. Before you take Vitamin C Arena
3. How to take Vitamin C Arena
4. Possible side effects
5. How to store Vitamin C Arena
6. Contents of the package and other information

1. WHAT IS Vitamin C ARENA AND WHAT IT IS USED FOR

Ascorbic acid, the active substance in Ascorbic Acid Arena, is a water soluble vitamin essential for the human body. The lack of it leads to a condition called scurvy that manifests through gingival bleeding, skin bleeding (petechiae), bone pain in the joints, anaemia, fatigue, predisposition to infections. Vitamin C Arena is indicated for the treatment of scurvy or its prevention in the case of conditions that require additional intake of ascorbic acid, when oral administration is not possible or the ascorbic acid deficiency is severe.

2. BEFORE YOU TAKE Vitamin C ARENA

Don't take Vitamin C ARENA if:

- are allergic (hypersensitive) to ascorbic acid or any of the other ingredients listed in section 6.1.
- if you have iron storage disorders (thalassemia, hemochromatosis, sideroblastic anaemia).
- if you have oxalic renal lithiasis (at doses greater than 1 g ascorbic acid per day).

Warnings and precautions

In some patients with glucose-6-phosphate-dehydrogenase deficiency it has been observed that (sometimes severe) haemolysis occurs when high doses of vitamin C (more than 4 g/day) are administered. Therefore, exceeding the recommended doses should be avoided.

In the case of the predisposition of kidney stones, the administration of high doses of vitamin C increases the risk of calcium oxalate calculations. Patients with recurrent urolithiasis should not be given more than 100-200 mg of vitamin C daily.

In patients with severe or end-stage renal failure (dialysis patients), the dose of 50-100 mg of vitamin C should not be exceeded, as a result of the increased risk of oxalates in the blood and the formation of oxalate crystals in the kidney. In patients with severe renal impairment, it is recommended to use lower doses of ascorbic acid.

Due to a mild stimulant effect, it is recommended that vitamin C not be taken at the end of the day.

The administration of doses of 1 g and above can increase the concentrations of ascorbic acid in the blood and urine so as to influence the biochemical parameters (glucose, uric acid, creatinine, inorganic phosphates). In general, chemical analysis methods based on colour reactions may be affected.

Vitamin C Arena with other drugs

Please tell your doctor if you are taking or have recently taken any other medicines, including OTC medicines.

Although the following interactions between vitamin C and other drugs have been described, their relevance to the recommended dose is unknown.

Vitamin C at a dose of 1 g per day increases the bioavailability of oral contraceptives. Corticosteroids intensify the oxidation of ascorbic acid. Calcitonin increases the percentage of consumption of vitamin C. Salicylates inhibit the active transport of vitamin C in the intestine. Tetracyclines inhibit intracellular metabolism and renal reabsorption of vitamin C. Acetylsalicylic acid, barbiturates, and tetracyclines promote the excretion of vitamin C into the urine. Several cases have been reported in which ascorbic acid reduced the effect of warfarin. Ascorbic acid may reduce the therapeutic effect of phenothiazines. The concentration of flufenazine may also be reduced. Chronic consumption of high doses of vitamin C may interfere with the disulfiram - ethyl alcohol system when administered concomitantly.

Ascorbic acid may increase the intestinal absorption of iron.

Ascorbic acid increases the absorption of aluminium from the gastrointestinal tract.

Pregnancy, breastfeeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

The Ascorbic acid is excreted into the breast milk and crosses the placental barrier through a simple diffusion mechanism. The effects of high doses on the foetus are unknown. Because the clinical data are insufficient, the medicine can be administered (without exceeding the recommended dose) during pregnancy or lactation only if absolutely necessary, at the doctor's advice.

Driving and usage of machines

Vitamin C Arena has no influence on the ability to drive or use machines.

3. How to use Vitamin C ARENA

Always use **Vitamin C Arena** exactly as your doctor has told you. You should talk to your doctor if you are not sure.

Vitamin C Arena will be given to you by a nurse or doctor directly in the vein.

Treatment of scurvy

Adults (including the elderly) and adolescents

500 mg up to 1 g per day.

Children

10 mg ascorbic acid/kg and day without exceeding 300 mg daily

Preventive treatment

Adults (including the elderly) and adolescents

200-500 mg daily

Children

5 - 7 mg ascorbic acid/kg and day without exceeding 100 mg daily

If you take more Vitamin C Arena than you need

Because the medicine is given to you by your medical staff, you are unlikely to get too high a dose of vitamin C. Gastrointestinal disorders including diarrhoea, hyperoxaluria, and oxalate stones in the case of an acidic urine may occur if you overdose. If you feel that you have been given too high a dose, talk to your doctor.

If you forget to take Vitamin C Arena

Because the medicine is being given to you by medical personnel, a dose is unlikely to be missed. However, if you feel that you have not been given a dose, talk to your doctor or nurse.

If you stop using Vitamin C Arena

After the prolonged administration of high doses of vitamin C, an increased urinary elimination of ascorbic acid may be associated with discontinuation of vitamin C, accompanied by symptoms of vitamin C deficiency.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Vitamin C Arena** can cause side effects, although not everybody gets them.

Ascorbic acid is generally well tolerated. At high doses, digestive disorders (epigastric burning sensation, diarrhea) or urination (the formation of uric acid, cystine and/or oxalate stones) may occur as well as episodes of hemolysis (in patients with glucose-6-phosphate-dehydrogenase deficiency).

Isolated skin and respiratory hypersensitivity reactions were observed.

In acute infections, the administration of ascorbic acid has been rarely associated with chills and increased body temperature in children.

Report side effects

If you have any side effects, talk to your doctor or pharmacist or nurse. These include any possible side effects not listed in this leaflet. You can also report side effects directly through the national reporting system, the details of which are published on the National Agency for Medicines and Medical Devices web site <http://www.anm.ro/>. By reporting side effects, you can help provide additional information on the safety of this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Vitamin C ARENA

Keep out of the reach and sight of children.

Store at temperatures below 25°C, in its original packaging.

Do not use **Vitamin C Arena** after the expiry date which is stated on the packaging after EXP. The expiration date refers to the last day of that month.

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

6. Content of the package and other information**What Vitamin C Arena contains**

- The active substance is ascorbic acid. One vial contains 750 mg ascorbic acid.
- The other components are: sodium hydrogencarbonate, water for injections.

How Vitamin C Arena looks like and the content of the package

Ascorbic Acid Arena comes in a clear, colourless to slightly yellow solution with no visible particles.

It is available in: packs of 5 vials and 200 vials of brown glass of 5 ml solution for injection.

Holder of the marketing authorisation

ARENA GROUP S.A.
Str. Ștefan Mihăileanu no. 31, code 024022, district 2,
Bucharest, Romania

Producer

Arena Group S.A.
Bd. Dunării no. 54, code 077190, Voluntari,
Ilfov county, Romania

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Information for the medical personnel

The solution should be used immediately after opening the vial. Do not use if the solution is not clear or has suspended particles.

Incompatibility

Ascorbic acid, solution for injection is incompatible with: iron salts, oxidizing substances and salts of heavy metals, especially copper. Incompatibility with aminophylline, bleomycin sulfate, erythromycin lactobionate, sodium naphthylline, nitrofurantoin, conjugated estrogens, sodium bicarbonate and sulfafurazole diethanolamine has also been reported. Occasionally, depending on the pH or concentration of the solution, incompatibility with sodium chloramphenicol has been reported.