

PATIENT INFORMATION LEAFLET

ASCORVIT 500 mg/5 mL solution for injection

Administered intramuscularly and intravenously.

Sterile

- **Active Ingredient:** In each ampoule (5mL); contains 500 mg vitamin C (Ascorbic acid).
- **Excipients:** Methyl paraben (E218), propyl paraben (E216), EDTA disodium, sodium hydroxide (pH adjuster), water for injection.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this patient information 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.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

What is in this leaflet:

1. *What ASCORVIT is and what is it used for?*
2. *What you need to know before you use ASCORVIT?*
3. *How to use ASCORVIT?*
4. *What are the possible side effects?*
5. *How to store ASCORVIT?*

Headings are covered.

1. What ASCORVIT is and what is it used for?

- Each ampoule contains 500 mg of vitamin C.
- ASCORVIT is a sterile and clear, colorless to yellow, particle-free solution in 5 mL transparent glass ampoules. It is presented in packages containing 5 ampoules in each box.
- In severe vitamin C (ascorbic acid) deficiency,
- it is used to eliminate or prevent vitamin C deficiency in cases where oral use is inadequate, not possible or should not be used.

2. What you need to know before you use ASCORVIT?

DO NOT USE ASCORVIT in below cases;

If;

- You are hypersensitive to vitamin C (ascorbic acid) or any of the other ingredients of ASCORVIT,
- You have hyperoxaluria (more oxalic acid in the urine than normal),

USE ASCORVIT CAREFULLY in the following cases:

- You have a disease such as excessive iron absorption from the intestines and iron accumulation in vital organs (especially the liver) (hemochromatosis) due to disorders in iron metabolism.
- In cases of kidney damage, kidney stones and kidney failure caused by calcium oxalate stone accumulation, vitamin C treatment should be discontinued in patients who develop calcium oxalate stones. Renal function should be monitored in all patients receiving vitamin C therapy.
- Those with kidney failure may be sensitive to the harmful effects of vitamin C at low doses. If you have kidney failure, do not use without consulting a doctor.
- Glucose-6-Phosphate Dehydrogenase (G6PD) enzyme deficiency and high-dose vitamin C should be used with caution in patients with G6PD deficiency as it may lead to hemolysis, a type of anemia.
- If you have various types of anemia;
 - Mediterranean anemia,
 - Sideroblastic anemia; excessive iron accumulation in blood cells called normoblasts in the bone marrow
 - Sickle cell anemia
- If you have a disease of abnormally high production of red blood cells in the bone marrow (polycythemia),
- If you have bone marrow cancer (leukaemia),
- If you have advanced cancer,
- If you are prone to a disease called inflammatory gouty arthritis, which causes the joint to become red, swollen and painful,

Consult your doctor before using vitamin C.

- If you are taking other single vitamin or multivitamin preparations, other medications, or are under medical care, consult your doctor before taking the product.

Situations That Distort Laboratory Test Results

Sugar measurements using glucose oxidase and copper sulfate may lead to false positive and false negative results in nitrite and bilirubin determinations and leukocyte (white blood cell) counts.

These warnings are valid for you, even at any time in the past, please consult your doctor.

Use of ASCORVIT with food and drink

It has no interaction with food and drink when administered by injection, but do not consume alcohol during your treatment with ASCORVIT.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

Vitamin C is considered safe during pregnancy when taken at the recommended dosage. However, because there are no adequate controlled human studies evaluating the risk of vitamin C therapy during pregnancy, the product should be used during pregnancy only when recommended by a physician. The recommended dose should not be exceeded, as long-term overdose may be harmful to the unborn baby.

If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.

Lactation

Consult your doctor or your pharmacist before using the drug.

Vitamin C passes into breast milk. It is not known whether taking high doses has a harmful effect on the baby, but it is theoretically possible. Therefore, it is recommended that breastfeeding mothers do not exceed the maximum daily requirement unless the expected benefit potential outweighs the risk.

Driving and using machines

ASCORVIT has no or negligible adverse effects on driving and using machines.

Important information about some excipients contained in ASCORVIT

This medicinal product contains 72.24 mg sodium in each 5 mL dose. This should be taken into consideration for patients on a controlled sodium diet.

ASCORVIT may cause allergic reactions (possibly delayed) and exceptionally bronchospasm due to its content of methyl paraben (E218) and propyl paraben (E216).

Use with other medicines

When used together with some drugs, the effect of ASCORVIT or the other drug used may change. Please tell your doctor if you are using the following medications:

- Disulfiram (a drug used to treat alcohol addiction)
- Warfarin and dicoumarol (oral medications that prevent or delay blood clotting)
- Iron drugs used in the treatment of anemia
- Desferrioxamine (a medicine used to treat iron overload disease)

- Cyclosporine (drug that suppresses the immune system)
- Indinavir (antiviral used in the treatment of AIDS)
- Ethinylestradiol (Birth control drug)
- Acetylsalicylic acid (Aspirin) and salicylic acid
- Isoprenaline (a drug that stimulates the sympathetic nervous system)
- Mexiletine (a medicine used against heart rhythm disorders)
- Barbiturates (sedative and sleep-inducing drug or group of drugs) such as primidone
- Amphetamine (A sympathetic nervous system stimulant drug used in attention deficit or sleep disorders)
- Tricyclic antidepressants (a group of drugs effective against depression)
- Fluphenazine and other phenothiazines (drug or group of drugs used in the treatment of psychiatric diseases such as schizophrenia and psychotic depression)
- Corticosteroids (Cortisone: A group of anti-inflammatory drugs used in the treatment of rheumatic diseases and many non-rheumatic diseases)
- Tetracyclines (a type of antibiotic used to treat infections)
- Amygdalin (medicine obtained from bitter almond used in cancer treatment)
- Aluminum (This interaction does not apply to individuals with normal renal function)

Alcohol: Alcohol consumption reduces the levels of ascorbic acid in the blood. The effects of concurrent use are unknown.

Vitamin C can interact with urine and blood sugar tests, causing inaccurate readings, but it has no effect on blood sugar levels. Consult the meter or test kit's instructions for use to determine whether vitamin C interacts and for guidance on accuracy in readings.

Vitamin C may also cause chemical interference in laboratory tests such as creatinine, carbamazepine, uric acid and inorganic phosphate analysis in urine and serum, and fecal occult blood analysis. Inform your physician or healthcare professional if such laboratory tests are planned while you are using this product.

If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about them.

3. How to use ASCORVIT?

Instructions for appropriate use and dose/administration frequency:

Unless your doctor gives separate advice:

Adults: In severe vitamin C deficiency, it is used at a dose of 500-1000 mg/day for up to 10 days.

It is used at a dose of 200-500 mg/day to eliminate or prevent vitamin C deficiency in cases where oral use is insufficient, impossible or inconvenient.

Your doctor will determine the dose of your drug and administer it to you depending on your illness.

Route and Method of administration:

It is given intramuscularly or intravenously. Intramuscular administration is preferred. When administered intravenously, it should be administered by slow infusion. Rapid intravenous injection may cause temporary drowsiness.

ASCORVIT application will be performed by your doctor or nurse.

Various age groups

Use in Children:

For the treatment of severe vitamin C deficiency, it is used at a dose of 100-300 mg/day, 1-2 times a day for 2 weeks-3 months, depending on the improvement of the symptoms.

Vitamin C is used intravenously at a dose of 15-25 mg/kg/day for premature babies and children aged 0-12 months who are fed intravenously and cannot be taken orally, and at a dose of 80 mg/day for children between the ages of 1-18.

Use in Elderly:

There is no special dosage for the elderly, it is the same as in adults.

Special use cases:

Renal failure:

It should be used with caution in patients with renal failure.

Hepatic failure:

No specific dosage recommendations are given in patients with hepatic impairment.

If you have the impression that the effect of ASCORVIT is too strong or weak, talk to your doctor or pharmacist.

If you use more ASCORVIT than you should:

There is no evidence that this product causes overdose when used as recommended.

Vitamin C intake from all other sources should be considered.

Clinical signs and symptoms, laboratory findings, and consequences of overdose are highly variable and depend on the individual's susceptibility and environmental conditions.

The general picture of vitamin C overdose is an increase in gastrointestinal disorders, including diarrhea, nausea and vomiting.

If these symptoms occur, treatment should be discontinued and a healthcare professional should be consulted.

If you have used more ASCORVIT than you should, talk to a doctor or pharmacist.

If you forget to use ASCORVIT

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with ASCORVIT is terminated

No negative effects are expected when treatment with ASCORVIT is terminated.

4. What are the possible side effects?

Like all medicines, side effects may occur in people who are sensitive to the ingredients contained in ASCORVIT.

If any of the following occur, stop using ASCORVIT and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital:

- Skin reactions such as rash, hives, itching,
- Hypersensitivity reactions,
 - Breathing difficulties
 - Severe skin reactions accompanied by low blood pressure
 - Swelling of the hands, feet, ankles, face, tongue and lips, or especially swelling of the mouth or throat that makes swallowing or breathing difficult (angioedema).
 - Immediate hypersensitivity reaction (anaphylactic shock)
 - Allergic asthma symptoms
 - Heart-related respiratory distress (cardio-respiratory distress)

If you have one of these, it means you have a serious allergy to ASCORVIT. You may need emergency medical attention or hospitalization.

Other side effects are listed as shown in the categories below:

Very Common: It can be seen in at least one in 10 patients.

Common: Effects seen 1 to 10 in 100 patients

Uncommon: Effects seen 1 to 10 in 1,000 patients

Rare: Effects seen in less than one in 1,000 patients, but in more than one in 10,000 patients.

Very Rare: Effects seen less than 1 in 10,000 patients

Unknown: Cannot be estimated from available data

Rare:

- Tenderness, pain, fever or swelling in the arms and legs
- Difficulty urinating

Very Rare:

- Destruction of red blood cells (in patients with glucose-6-phosphatase deficiency)
- Skin reactions such as rash, hives, itching,
- Hypersensitivity reactions,
 - Breathing difficulties
 - Severe skin reactions accompanied by low blood pressure
 - Swelling of the hands, feet, ankles, face, tongue and lips, or especially swelling of the mouth or throat that makes swallowing or breathing difficult (angioedema).
 - Immediate hypersensitivity reaction (anaphylactic shock)
 - Allergic asthma symptoms
 - Heart-related respiratory distress (cardio-respiratory distress)
- Diarrhea, nausea, vomiting, abdominal pain, indigestion

Unknown:

- Headache, dizziness, fatigue, sleep disturbance
- Flushing or redness
- Diuresis (increase in urine excretion rate and therefore volume)
- Hyperoxaluria (more oxalic acid in the urine than normal)
- Kidney stone formation
- Injection site reactions

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ASCORVIT?

Keep it in its packaging and out of sight and reach of children.

Store at room temperature below 25°C, protected from light.

Use in compliance with the expiry date.

Do not use ASCORVIT after the expiration date on the packaging.

If you notice any defects in the product and/or its packaging, do not use ASCORVIT.

Do not throw away expired or unused drugs! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Marketing Authorization Holder:

Haver Trakya İlaç San. ve Tic. A.Ş.
Ulaş OSB Mah. D100 Cad. No:28/1, Ergene 2 OSB
Ergene/TEKİRDAĞ

Manufacturing Site:

Haver Trakya İlaç San. ve Tic. A.Ş.
Ulaş OSB Mah. D100 Cad. No:28/1, Ergene 2 OSB
Ergene/TEKİRDAĞ
Phone: (0282) 655 55 05

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