**PATIENT INFORMATION LEAFLET**

**ANTOKSİ-C 500 mg/5 ml Solution for I.V. Injection**
**Administered intravenously**
**Sterile**

- ***Active Substance:*** Each ampoule (5 ml) contains 500 mg vitamin C (ascorbic acid). There is 100 mg active substance in unit dosage (1 ml).
- ***Excipients:*** Metyl paraben (E218), propyl paraben (E216), sodium hyrdoxide, 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 the written instructions exactly. Do not use* ***higher or lower*** *dose than the recommended dose.*

**What is in this leaflet**



**1.** ***What ANTOKSİ-C is and what it is used for?***

Each ampoule contains 500 mg of vitamin C as an active ingredient.
ANTOKSİ-C is available in clear glass ampoules.
ANTOKSİ-C is used in vitamin C deficiency where injection therapy is required.

**2.** ***What you need to know before use ANTOKSİ-C ?***

**DO NOT use ANTOKSİ-C in the following situations:**

If;
-you are allergic (hypersensitive) to any of the ingredients of ANTOKSİ-C,
-you are on dialysis, have severe kidney failure or impaired kidney function,
-you have kidney stones or have had kidney stones before,
-you have hyperoxaluria (urinary oxalic acid is more than normal)
-you have a disease such as excessive iron absorption from the intestines due to disorders in iron metabolism and iron accumulation (hemochromatosis) in vital organs (especially the liver).

**USE ANTOKSİ-C CAREFULLY in the following cases**

- Vitamin C overdose (>2 g/day) can significantly increase oxalate levels in blood and urine. This may lead to kidney stones, kidney tissue damage and/or kidney failure, which are observed due to calcium oxalate accumulation. Do not exceed the recommended dose.
- People with mild or moderate renal impairment 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.
- If you have an enzyme disease called glucose-6-phosphatase deficiency, it can cause anemia (hemolytic anemia) or clotting (intravascular coagulation) for widespread vein. Do not take a higher dose than recommended.
- If you have a tendency to calcium-oxalic kidney stone disease or you have recurrent kidney stone disease, your vitamin C consumption should not exceed 100-200 mg per day.
- 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 an abnormally increased disease (polycythemia) of excessive red blood cell production in the bone marrow,
- If you have bone marrow cancer (leukemia),
- If you have advanced cancer.
- If we have a tendency to the disease called inflammatory gouty arthritis, which causes the joint to become red and swollen and sore,consult your doctor before using vitamin C.
- Consult your doctor before taking the product if you are using other single vitamin or multivitamin preparations, other medicines, or under medical care.
- The use of vitamin C can lead to incorrect results when taking a sugar test from urine. Before the test, consult the instruction manual of the test kit.
- Vitamin C can interact with laboratory tests, leading to false readings. Inform your doctor when taking this product and planning laboratory tests.

Please consult your doctor if these warnings apply to you, even at any time in the past.

**Pregnancy**
*Consult your doctor or pharmacist before using this medication.*

Vitamin C is considered safe during pregnancy when taken in the recommended dosage.
However, since there are not enough controlled human studies evaluating the risk of vitamin C treatment during pregnancy, the product should only be used when recommended by the physician during pregnancy. The recommended dose should not be exceeded as long-term overdose can be harmful to the unborn baby.

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

**Lactation**
*Consult your doctor or pharmacist before using this medication.*

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 is greater than the risk.
**Ability to drive and use machines**
ANTOKSİ-C has no negative effects on the ability to drive and use machines or is negligible.

**Important information about some of the excipients contained in ANTOKSİ-C**
This medicinal product contains less than 1 mmol (23 mg) sodium per "dose"; in other words, it does not “contain sodium”.

Since ANTOKSİ-C contains methyl paraben (E218) and propyl paraben (E216), it may cause allergic responses (possibly delayed) and unexpected narrowing of the bronchi.

**Use in combination with other drugs**
When used with some medicines, the effect of ANTOKSİ-C or other medication may change. If you are using the following medicines, please tell your doctor:

- Disulfiram (used to treat alcohol dependence)
- Warfarin and dicumarol (oral medications that prevent or delay blood clotting)
- Iron (an essential mineral used to treat anemia)
- Desferrioxamine (drug used to treat iron overload)
- Cyclosporine (a drug that suppresses the immune system)
- Indinavir (antiviral drug used in AIDS treatment)
- Ethinylestradiol (Birth control drug)
- Acetylsalicylic acid (Aspirin) and salicylic acid
- Isoprenaline (a drug that stimulates the sympathetic nervous system)
- Mexiletine (a drug used against heart rhythm disorder)
- Barbiturates, such as Primidon (sedative and sleep medication or group of drugs)
- Amphetamine (a sympathetic nervous system stimulant drug used in attention deficits or sleep disorders)
- Tricyclic antidepressants (group of drugs effective against mental breakdown)
- Flufenazin and other phenothiazines (drug or group of drugs used in the treatment of psychiatric diseases such as schizophrenia and psychotic depression)
- Corticosteroids (Cortisone: Anti-inflammatory drug group used in the treatment of rheumatic diseases and many non-rheumatic diseases)
- Tetracyclines (a type of antibiotic used to treat infections)
- Amygdalin (medicine from bitter almond used in cancer treatment)
- Aluminum (This interaction is not valid for individuals with normal kidney function)

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

Vitamin C can interact with tests that measure urine and blood sugar, causing erroneous readings, but has no effect on blood sugar levels. To determine if vitamin C is interacting and for guiding accuracy in reading, see the instructions for using the meter or test kit.

Vitamin C can also cause chemical interactions in urine and serum creatinine, carbamazepine, uric acid and inorganic phosphate analysis and fecal occult blood analysis laboratory tests. If such laboratory tests are planned while using this product, inform your doctor or healthcare professional.

*If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.*

**3.** ***How to use ANTOKSİ-C?***

**Instructions regarding correct use and dosage/administration frequency:**
Unless your doctor makes a separate recommendation:
In adults and children over 12 years old: 500-1000 mg per day
It should not be used more than 2 ampoules (1000 mg vitamin C/day) per day.

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

**Method of administration:**
It is administered through a vein.

**Different age groups:**
**Usage in children:**
It is not recommended for use in infants and children.

**Usage in elderly**
No specific dose recommendations have been made.

**Conditions of special use:**
**Renal and hepatic failure**
It should not be used in patients with kidney failure. No specific dose recommendations have been made for patients with hepatic failure.

*Talk to your doctor or pharmacist if you have the impression that the effect of ANTOKSİ-C is too strong or too weak.*

**If you use more ANTOKSİ-C than you should:**
There is no evidence that this product causes an overdose when used as recommended.

Vitamin C intake from all other sources should be considered.

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

In the general picture of vitamin C overdose there 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 use more ANTOKSİ-C than you should, talk to a doctor or pharmacist.*

**If you forget to use ANTOKSİ-C:**
*Do not take a double dose to compensate forgotten dose.*

**If ANTOKSİ-C treatment stopped, effects may occur:**
No known effects are expected due to sudden cessation of treatment.

**4. Possible side effects**
Like all other medicines, ANTOKSİ-C may cause side effects in patients with hypersensitivity to any component of the drug.

**If one of following occurs, stop using ANTOKSİ-C and tell your doctor immediately or consult nearest emergency room:**

- Skin reactions such as rash, hives, itching
- Hypersensitivity reactions,
    - Breathing difficulties
    - Severe skin reactions with low blood pressure
    - Swelling of the hands, feet, wrists, face, tongue and lips, or swelling of the mouth or throat, in particular, making it difficult to swallow or breathe (angioedema).
    - Sudden hypersensitivity response (anaphylactic shock)
    - Allergic asthma symptoms
    - Heart-acquired respiratory distress (cardio-respiratory distress)

All of these are very serious side effects.
If you have one of these, you have a serious allergy to ANTOKSİ-C. You may need urgent medical attention or hospitalization.

Other side effects are listed as shown in the following categories:
Very common: It can be seen in at least 1 of 10 patients.
Common: Less than one in 10 patients, but more than one in 100 patients.
Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.
Rare: Less than one in 10,000 patients, but more than one in 10,000 patients.
Very rare: Less than one in 10,000 patients can be seen.
Unknown: Cannot be estimated from available data.

**Rare:**
- Sensitivity, 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 with low blood pressure
    - Swelling of the hands, feet, wrists, face, tongue and lips, or swelling of the mouth or throat, making it difficult to swallow or breathe (angioedema).
    - Sudden hypersensitivity response (anaphylactic shock),
    - Allergic asthma symptoms
    - Heart-acquired respiratory distress (cardio-respiratory distress)

- Diarrhea, nausea, vomiting, abdominal pain, indigestion.

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

*Inform your doctor or pharmacist if you encounter any side effects not mentioned in this instructions for use.*

**5. How to store ANTOKSİ-C ?**
*Store ANTOKSİ-C in its original packaging and keep out of the reach and sight of children.*

Store at room temperature under 25°C.

**Use in accordance with expiration dates.**
*Do not use ANTOKSİ-C after the expiration date on the packaging.*

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

Do not use ANTOKSİ-C if you notice defects in the product and/or packaging.

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