

PATIENT INFORMATION LEAFLET

SELOVITA-C 500 mg/5 ml I.M./I.V./S.C. Solution For Injection Ampoule

Administered intramuscularly, intravenously or subcutaneously.

- **Active substance:** Each 5 ml ampoule contains 500 mg Vitamin C (ascorbic acid).
- **Excipients:** Methyl paraben, propyl paraben, sodium hydroxide, water for injection

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

- *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 signs of illness are the same as yours.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high** or **low** doses other than the recommended dosage.*

What is in this leaflet:

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

Headings are included.

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

- Each ampoule contains 500 mg of vitamin C.
- SELOVITA-C is presented in 5 ml transparent glass ampoules in packages containing 5 ampoules in each box.
- SELOVITA-C is used in the acute deficiency of Vitamin C or when it is not possible to use it orally (eg wound healing, burns, inflammatory microbial diseases, trauma, thyroid poisoning and after surgery). It is also used as an adjunct to the treatment of idiopathic methemoglobinemia (a type of blood disease).

2. What you need to know before you use SELOVITA-C

DO NOT USE SELOVITA-C;

If;

- You are hypersensitive to vitamin C or any of the other ingredients of SELOVITA-

C,

- You have hyperoxaluria (urinary oxalic acid is more than normal),
- You have kidney stones accompanied by aciduria (urine being acidic) or urine pH normal and the presence of oxalic acid in the urine.

USE SELOVITA-C CAREFULLY;

If;

- You have kidney problems,
- You have various types of anemia (median anemia, sideroblastic anemia, sickle cell anemia), if there is an accumulation of iron in your major organs (hemochromatosis), especially in the liver, if the amount of red blood cells in your blood has increased (polycythemia) or leukemia (cancer of blood cells)
- You have G6PD (glucose-6-phosphate dehydrogenase) enzyme deficiency (this deficiency is a vital enzyme in blood sugar metabolism is missing or not active enough)
- You have heart or lung disease,
- You have diabetes (Vitamin C may cause inaccuracies in urine sugar test results. Vitamin C should be stopped a few days before the test)
- You have advanced cancer disease,
- You smoke.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Use of SELOVITA-C with food and drink

Since it is administered by injection, it does not interact with food and drink, but do not use alcohol during your treatment with SELOVITA-C.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

Vitamin C passes to the offspring in the womb. The medicine can be used if your doctor thinks that SELOVITA-C benefits you more than its possible drawbacks.

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

Breast-feeding

Consult your doctor or pharmacist before using this medication.

Vitamin C passes into breast milk. The medicine can be used if your doctor thinks that SELOVITA-C benefits you more than its possible drawbacks.

Driving and using machines

Injection of SELOVITA-C will not affect your ability to drive or operate vehicles

Important information about some excipients found in the composition of SELOVITA-C

This medicinal product contains approximately 66 mg of sodium in every 5 ml dose. This should be considered for patients on a controlled sodium diet.

SELOVITA-C may cause allergic responses (possibly delayed) and unexpected narrowing of the bronchi due to its methyl paraben and propyl paraben content.

Use with other medicines

The effect of SELOVITA-C or other drug may change when used with some medicines. If you are using the following medicines, please tell your doctor:

- Contraceptives
- Medicines to prevent blood clotting, such as warfarin and dicumarol.
- Iron medicines used in anemia treatment
- Desferrioxamine (a medicine used to treat iron overload)
- Isoprenaline (a drug that stimulates the sympathetic nervous system)
- Disulfiram (a drug used to treat alcohol dependence)
- Mexiletine (a drug used against heart rhythm disorder)
- Barbiturates such as Primidon (tranquilizer and sleep medication or drug group)
- Amphetamine (a drug that stimulates the sympathetic nervous system)
- Tricyclic antidepressants (group of drugs effective against mental breakdown)
- Flufenazin and other phenothiazines (drug or group of drugs used to treat psychiatric diseases such as schizophrenia and psychotic depression)
- Aspirin
- Medicines used in the treatment of epilepsy (eg phenytoin)
- Tetracycline, an antibiotic
- Appetite suppressors

If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.

3. How to use SELOVITA-C

Instructions for appropriate use and dose / administration frequency:

Your doctor will determine the dose of your medicine depending on your illness. It is recommended as 100-250 mg 1 or 2 times a day in adults. In severe cases, doses up to 1-2 grams can be administered.

Special dosage instructions

In idiopathic methemoglobinemia, divided doses of 300-600 mg daily are recommended.

Method of administration:

SELOVITA-C can be given intramuscularly (IM), subcutaneously (SC) or intravenously (IV). Intramuscular (IM) administration is preferred. When applying intravenously (IV), it should be administered by slow infusion because rapid intravenous injection may temporarily cause drowsiness.

SELOVITA-C application will be carried out by your doctor or nurse.

Various age groups

Use in Children:

General dosage administration in the treatment of ascorbic acid deficiency is 100 mg to 300 mg daily..

Use in Elderly:

There is no specific dosage for its use in the elderly, as for adults.

Special use cases

Renal failure:

The recommended dose for patients undergoing chronic hemodialysis is 100-200 mg / day. Caution should be exercised when administering SELOVITA-C to patients with impaired kidney function or a history of kidney stones.

Hepatic failure:

No dose adjustment is required in patients with hepatic impairment.

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

If you have used more SELOVITA-C than you should

High doses of vitamin C can cause kidney stones if your diarrhea and your urine are acidic. Doses of 600 mg or more can cause you to urinate frequently. If any of these symptoms bothers you, please consult your doctor.

If you have used more than you should use from SELOVITA-C, talk to a doctor or pharmacist.

If you forget to use SELOVITA-C

Do not take double doses to compensate for forgotten doses.

Your doctor or nurse will provide you with the vitamin C you need. If you want to learn more about this topic, talk to your doctor.

Effects which may occur when treatment with SELOVITA-C is discontinued

No negative effects are expected when treatment with SELOVİTA-C is terminated.

4. What are the possible side effects?

As with all medicines, there may be side effects in people who are sensitive to the ingredients of SELOVİTA-C.

If one of the following occurs, stop using SELOVİTA-C and report it to your doctor IMMEDIATELY or contact the emergency department of the nearest hospital:

- Allergic reactions such as rash, itching, difficulty breathing, chest tightness, swelling of the mouth, face, lips and tongue
- Kidney stone formation, hyperoxaluria (excessive amount of oxalate in urine), difficulty in urination, diuresis (increase in urine urination rate and therefore volume)

These are all very serious side effects. You may need an emergency medical intervention or hospitalization.

If you notice any of the following, tell your doctor right away or contact to the emergency service of the nearest hospital:

- Stomach cramping, diarrhea, nausea or vomiting
- Sensitivity, pain, fever or swelling in the arms and legs

Serious reactions, pain, swelling at the injection site. These are all serious side effects. Emergency medical attention may be required.

Tell your doctor if you notice any of the following:

- Headache, dizziness or lightheadedness, fatigue, sleep disturbance
- Flushing or rash

These are mild side effects of SELOVİTA-C.

If you encounter any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. How to store SELOVİTA-C

Keep SELOVİTA-C out of the sight and reach of children, and in its packaging.

Store at room temperature below 25°C.

Use in compliance with the expiry date.

Do not use SELOVİTA-C after the expiration date stated on the packaging

Do not use SELOVİTA-C if you notice any damage in the product and/or its package.

Marketing Authorization Holder

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