SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drug substance:

Each 5 ml ampoule contains 500 mg Vitamin C (ascorbic acid).

Excipients:

Methyl paraben	4 mg
Propyl paraben	0,5 mg

Please see section 6.1 for excipients.

3. PHARMACEUTICAL FORM

Solution for injection
Sterile, apyrogen and clear solution in transparent glass ampoule

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

SELOVİTA-C is used in the acute deficiency of Vitamin C or in cases where its oral use is contraindicated (for example, wound healing, burns, infections, trauma, thyrotoxicosis and post-operative). It is also used as an adjunct to the treatment of idiopathic methemoglobinemia.

4.2. Posology and method of administration

Posology /administration frequency and duration

It is recommended as 100-250 mg once or twice a day in ascorbic acid deficiency in adults. In severe cases, doses up to 1-2 grams can be administered.

Other

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

Method of administration:

SELOVİTA-C can be given intramuscularly~~, subcutaneously~~ or intravenously. Intramuscular administration is preferred. When applying intravenously, it should be administered by slow infusion because rapid intravenous injection can temporarily cause drowsiness.

Additional information for special populations:

Renal failure:

The recommended dose for patients undergoing chronic hemodialysis is 100-200 mg / day. Caution should be exercised when administering SELOVİTA-C to patients with impaired renal function or a history of kidney stones (see section 4.4. Special use warnings and

precautions)

Hepatic failure:

No dose adjustment is required in patients with hepatic impairment.

Pediatric population:

As long as the clinical symptoms continue in therapeutic applications, the dose is 100 - 300 mg (1-3 ml) per day. The daily dose for preventive treatment is 30 mg.

Geriatric population:

There is no specific dosage advice for the elderly.

4.3. Contraindications

SELOVİTA-C should not be used in people who are known to be hypersensitive to any of the substances it contains.

It should not be used in case of hyperoxaluria.

Vitamin C should not be used in cases of kidney stones accompanied by aciduria or normal urine pH and oxaluria.

4.4. Special warnings and special precautions for use

High doses of ascorbic acid raise urinary oxalate levels and can cause the formation of calcium oxalate stones in the kidney. Patients with impaired kidney function or a history of kidney stones may be more susceptible to this effect.

Since ascorbic acid increases iron absorption, high doses can be dangerous in patients with hemochromatosis, thalassemia, polycythemia, leukemia or sideroblastic anemia. In case of iron overload disease, ascorbic acid intake should be kept to a minimum.

Caution should be exercised since hemolysis may occur when ascorbic acid is given to patients with glucose-6-phosphate dehydrogenase (G6PD) enzyme deficiency.

It has been demonstrated that high doses of ascorbic acid are associated with sickle cell crises in sickle cell anemia patients.

Chronic use of high doses of ascorbic acid can lead to increased metabolism of the drug. So, when the dosage is suddenly reduced, withdrawal symptoms may develop. In such a case, the high dosage should be restored and the dosage should be reduced more slowly.

When high-potency vitamins are infused too quickly, pain and rarely thrombophlebitis may develop along the vein due to chemical irritation. Therefore, the solution should be infused slowly and care should be taken to avoid extravasation during the infusion. As with all parenteral solutions, care should be taken not to overload the circulatory system, especially in patients with heart and lungs.

The diabetogenic effect of ascorbic acid is still controversial. However, blood glucose concentration should be monitored periodically in patients receiving long-term SELOVİTA-C therapy, especially in the initial period of treatment. The use of ascorbic acid in diabetic patients can lead to false results in urine glucose assay tests. Therefore, ascorbic acid should be discontinued a few days before such tests are performed.

Theoretically, high doses of ascorbic acid can cause gouty arthritis in susceptible patients due to its effect on uric acid excretion.

It is thought that ascorbic acid can aggravate rapidly multiplying and widely spread tumors. Therefore, caution should be exercised when prescribing ascorbic acid in advanced cancers.
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.
Since SELOVİTA-C contains methyl paraben and propyl paraben, it can cause allergic reactions (possibly delayed) and exceptional bronchospasm.
Yellowing may occur in ascorbic acid solutions when exposed to light. Although this color change does not reduce the therapeutic activity of SELOVİTA-C, it is recommended to keep it in the packaging of the ampoules.

4.5. Interaction with other medicinal products and other forms of interaction

Aspirin: In concurrent use, an increase in urinary excretion of ascorbic acid and a decrease in excretion of aspirin occur. Aspirin has been found to reduce ascorbic acid absorption by approximately 1/3.
Dicumarol: There is an exceptional case in which prothrombin time is shortened after ascorbic acid intake.
Warfarin: Some cases have been reported in which ascorbic acid appears to reduce the effects of warfarin.
Ethinylestradiol: Ascorbic acid in a daily dosage of 1 gram increases the bioavailability of ethinylestradiol from oral contraceptive preparations. Thus, low dose contraceptives become similar to higher doses in terms of pharmaceutical and toxicological properties. This effect is especially important when ending ascorbic acid supplementation, because in this case, a decrease in hormone absorption can cause sudden bleeding and even deterioration in contraception.
Iron (oral): Ascorbic acid can increase iron absorption.
Desferrioxamine: Ascorbic acid may increase the excretion of iron when given concomitantly with desferrioxamine. However, patients receiving concomitant therapy have had cardiomyopathy and congestive heart failure. This can be explained by the increase in iron accumulation in the visceral organs by ascorbic acid mobilizing iron from the spleen and other reticuloendothelial tissues.
Isoprenaline: The chronotropic effect of isoprenaline decreases when co-administered with ascorbic acid.
Alcohol: Alcohol reduces the levels of ascorbic acid in the blood.
Disulfiram: The use of ascorbic acid in chronic or high doses may interfere with the disulfiram-alcohol interaction in concomitant use.
Mexiletin: When high doses of ascorbic acid and mexiletine are administered simultaneously, renal excretion of mexiletine may accelerate.
Barbiturates (Primidone): When administered simultaneously with barbiturates (primidone), urinary excretion of ascorbic acid may increase.
Amphetamine and tricyclic antidepressants: Ascorbic acid reduced renal tubular reabsorption of amphetamines and tricyclic antidepressants.
Flufenazin and other phenothiazines: Ascorbic acid has been reported to reduce the therapeutic effect of phenothiazines. Flufenazine concentration may also drop.
Laboratory tests: Ascorbic acid interacts with laboratory tests involving oxidation and reduction reactions such as glucose oxidase test, copper sulfate test due to its reductive nature. Ascorbic acid is an obstacle in the determination of serum transaminases and lactic

dehydrogenase with an autoanalyzer. It may also affect some tests for the determination of latent blood and serum theophylline levels.
Drugs that cause tissue desaturation of ascorbic acid include cigarette-induced nicotine, some appetite suppressors, phenytoin, some anticonvulsant drugs, and tetracyclines. High doses of ascorbic acid can lead to acidification of urine, thereby unexpectedly undergoing renal tubular reabsorption of drugs of acidic nature, resulting in excessive response. On the other hand, basic drugs may show reduced reabsorption, resulting in a decrease in the therapeutic effect.

Additional information on special populations

No interaction studies have been conducted on special populations.

Pediatric population:

No interaction studies have been conducted regarding the pediatric population.

4.6. Pregnancy and lactation

General advice

Pregnancy category: C

Women with child-bearing potential / Contraception

Contraception may deteriorate when high doses of SELOVİTA-C are combined with oral contraceptives containing ethinylestradiol. (see section 4.5. Interactions with other medicinal products and other forms of interaction)

Pregnancy

Ascorbic acid passes through the placenta. With the intake of high doses of ascorbic acid during pregnancy, the fetus can adapt to it and develop ascorbic acid deficiency in the form of postpartum abstinence syndrome. Therefore, high doses of the drug (e.g. doses over 1 gram) should not be used in pregnant women or those who are likely to become pregnant unless the expected benefits are greater than the potential risk.

Lactation

Ascorbic acid passes into breast milk. It is not known whether taking a high dose will have a harmful effect on the baby, but theoretically this is possible. Therefore, it is recommended that nursing mothers do not exceed the maximum daily requirement unless the expected benefit exceeds the potential risk.

Fertility

It is not known whether SELOVİTA-C affects its reproductive ability.

4.7. Effects on ability to drive and use machines

SELOVİTA-C has no effect on the ability to drive and use machines.

4.8. Undesirable effects

As excess vitamin C is excreted from the body, it has a low potential for side effects. Undesirable effects due to SELOVİTA-C observed during clinical trials are listed according to the frequency levels below.
Very common (≥ 1/10), common (≥ 1/100 and < 1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10.000 and <1/1000), very rare (<1/10.000) and unknown (cannot be estimated from

the available data.).

Immune system diseases
Rare: allergic reactions such as rash, itching, difficulty breathing, chest tightness, swelling of the mouth, face, lips and tongue.

Nervous system disorders
Not known: headache, dizziness or lightheadedness, fatigue, sleep disturbance

Gastrointestinal diseases
Not known: stomach cramp, diarrhea, nausea or vomiting

Skin and subcutaneous tissue disorders
Not known: flushing (redness) or redness

Musculoskeletal and Connective Tissue Disorders
Rare: Sensitivity, pain, fever or swelling in the arms and legs.

Kidney and urinary diseases
Rare: Difficulty in urinationNot known: kidney stone formation, hyperoxaluria, diuresis

General disorders and diseases related to the application site
Rare: Severe reactions at the injection site Not known: pain, swelling at the injection site

4.9. Overdose
High doses can lead to gastrointestinal disorders, including diarrhea. High doses can also cause hyperoxaluria and kidney stone formation if the urine is acidic. Doses of 600 mg or more daily have a diuretic effect. In case of overdose, treatment should be stopped and symptomatic treatment should be carried out.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ascorbic acid (Vitamin C) and combinations
ATC code: A11GA01

Ascorbic acid, a water-soluble vitamin, is essential for the formation of collagen and intercellular material. Therefore, it is necessary for the development of cartilage, bone, teeth and wound healing. It also plays a role in the conversion of folic acid to folinic acid, facilitates the absorption of iron from the gastrointestinal tract. It is effective in the formation of hemoglobin and maturation of erythrocytes.

5.2 Pharmacokinetic properties
General properties

Absorption: Ascorbic acid is absorbed mainly through the sodium-dependent active transport mechanism in the upper part of the small intestine. When ascorbic acid is present in high concentrations, absorption occurs through passive diffusion. After oral administration of doses up to 180 mg, it is absorbed in up to 70% 90%. After doses such as 1-12 g, the absorbed ascorbic acid ratio decreases from approximately 50% to 15%, but the amount of absorbed substance continues to increase.
Distribution: The binding rate of ascorbic acid to plasma proteins is approximately 24%. Serum concentrations are normally 10 mg / L (60 µmol / L). Concentrations below 6 mg / L (35 µmol / L) indicate that vitamin C intake is not always at adequate levels. Concentrations below 4 mg / L (20 µmol / L) indicate an inadequate vitamin intake. In clinical ascorbic acid deficiency, serum concentrations are below 2 mg / L (10 µmol / L).
Biotransformation: Ascorbic acid is partially metabolised to oxalic acid via dehydroascorbic acid. However, ascorbic acid is excreted largely unchanged in urine and feces when taken in excessive amounts. Ascorbic-acid-2 sulfate is also found in the urine as a metabolite.
Elimination: Physiological body stores are approximately 1500 mg. Excretion of ascorbic acid; its half-life is related to the mode of administration, the amount administered, and the rate of absorption. After an oral dose of approximately 50 mg of vitamin C, its half-life is about 14 days, and approximately 13 hours after a dose of 1 g. After administration of 500 mg sodium ascorbate intravenously, its half-life is approximately 6 hours. When taking vitamin C in amounts less than 1-2 g / day, the main route of excretion is the kidneys. At doses exceeding 3 days, increased amounts are excreted unchanged in the feces.

5.3 Preclinical safety data

No additional information is available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl paraben
Propyl paraben
Sodium hydroxide
Water for injection

6.2 Incompatibilities

Iron salts, oxidizing agents, heavy metal salts; especially incompatible with copper salts. Ascorbic acid injections have been reported to be incompatible with aminophylline, bleomycin sulfate, erythromycin lactobionate, nafsilin sodium, doxapram hydrochloride, cefazolin sodium, nitrofurantoin sodium, conjugated estrogens, sodium bicarbonate and sulfafurazole diethanolamine. The incompatibility, rarely developed due to pH or concentration, has been observed with chloramphenicol sodium succinate, chlorothiazide sodium, hydrocortisone sodium succinate and penicillin G potassium.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Store at room temperature below 25 ° C. Protect from light.

6.5 Nature and contents of container
The product filled in transparent Type I glass ampoules which is packaged in a cardboard box with a plastic separator containing 5 ampoules of 5 ml.

6.6 Instructions for use and handling and disposal
Unused products or waste materials must be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

7. MARKETING AUTHORISATION HOLDER
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2016/676

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
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