

1. NAME OF THE MEDICINAL PRODUCT

{(Harvit C) Ascorbic acid 500mg Injection}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[Each ampoule contains:

Ascorbic acid 500mg/5ml]

3. PHARMACEUTICAL FORM

Solution for Injection.

4. Clinical particulars

4.1 Therapeutic indications

The prevention and treatment of scurvy, or other conditions requiring vitamin C supplementation, where the deficiency is acute or oral administration is difficult.

4.2 Posology and method of administration

Posology

Route of Administration: Parenteral

Adults: 0.5 to 1g daily for scurvy, 200 to 500mg daily for preventative therapy.

Children: 100 to 300mg daily for curative purposes, or 30mg daily for protective treatment.

Elderly: No special dosage requirements have been suggested.

Method of administration

I.M/I.V Route

4.3 Contraindications

Hypersensitivity to the active substance or Hyperoxaluria.

4.4 Special warnings and precautions for use

Ascorbic acid should be given with care to patients with underlying renal failure due to the risk of formation of renal oxalate calculi. Tolerance may be induced in patients taking high doses. Large doses of Ascorbic Acid have resulted in haemolysis in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency

4.5 Interaction with other medicinal products and other forms of interaction

Drugs which induce tissue desaturation of ascorbic acid include aspirin, nicotine from cigarettes, alcohol, several appetite suppressants, iron, phenytoin, some anti-convulsant drugs, the oestrogen component of oral contraceptives and tetracycline. Large doses of ascorbic acid may cause the urine to become acidic causing unexpected renal tubular reabsorption of acidic drugs, thus producing an exaggerated response. Conversely basic drugs may exhibit decreased reabsorption resulting in a decreased therapeutic effect. Large doses may reduce the response to oral anticoagulants.

It has been reported that concurrent administration of ascorbic acid and fluphenazine has resulted in decreased fluphenazine plasma concentrations.

Ascorbic acid is a strong reducing agent and interferes with numerous laboratory tests based on oxidation – reduction reactions. Specialised references should be consulted for specific information on laboratory test interferences caused by ascorbic acid.

Ascorbic acid given in addition to desferrioxamine in patients with iron overload to achieve better iron excretion may worsen iron toxicity, particularly to the heart, early on in the treatment when there is excessive tissue iron. Therefore it is recommended that in patients with normal cardiac function ascorbic acid should not be given for the first month after starting desferrioxamine. Ascorbic acid should not be given in conjunction with desferrioxamine in patients with cardiac dysfunction.

Aspirin can reduce the absorption of ascorbic acid by approximately a third and decreases urinary excretion by about half. The clinical importance of this is uncertain.

Patients with kidney failure given aluminium antacids and oral citrate can develop a potentially fatal encephalopathy due to marked rise in blood aluminium levels. There is evidence that vitamin C may interact similarly.

Oral contraceptives lower serum levels of ascorbic acid.

4.6 Pregnancy and Lactation

Pregnancy, Lactation, Fertility:

Ascorbic acid in doses greater than 1g daily should not be taken during pregnancy since the effect of large doses on the foetus is unknown. Ascorbic acid is excreted in breast milk, but there is no evidence of any hazard.

4.7 Effects on ability to drive and use machines

Ascorbic acid injection is unlikely to affect the patient's ability to drive or use machinery.

4.8 Undesirable effects

Large doses may cause gastrointestinal disorders including diarrhoea. Large doses may also result in hyperoxaluria and renal oxalate calculi may form if the urine becomes acidic. Doses of 600mg or more daily have a diuretic action. Induced tolerance with prolonged use of large doses can result in symptoms of deficiency when intake is reduced to normal.

4.9 Overdose

No case of overdose has been reported. If overdose occurs the patient should be monitored for evidence of toxicity and standard supportive treatment applied as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: {Antioxidants}, ATC code:

{A11G A01}

Ascorbic acid, a water-soluble vitamin, is essential for formation of collagen and intercellular material, and therefore necessary for the development of cartilage, bone, teeth and for the healing of wounds. It is also essential for the conversion from folic acid to folinic acid, facilitates iron absorption from the gastrointestinal tract and influences haemoglobin formation and erythrocyte maturation.

5.2 Pharmacokinetic properties

Distribution – widely distributed in body tissues with about 25% bound to plasma proteins. Large amounts are present in leucocytes and platelets. Ascorbic acid crosses the placenta.

Metabolism – readily oxidised to dehydroascorbic acid where some is metabolised to oxalic acid and the inactive ascorbate - 2 - sulphate. Metabolic turnover appears to be greater in females than males.

Excretion – large doses are rapidly excreted in the urine when in excess of the requirements of the body and after an intravenous dose, about 40% is excreted in 8 hours, which is increased to about 70% after tissue saturation. The amount of unchanged drug is dose dependent; in women the excretion of ascorbic acid appears to vary with the stage of the menstrual cycle and it is decreased when taking oral contraceptives.

Ascorbic acid is excreted in breast milk.

Oxalic acid and ascorbate - 2 - sulphate are excreted in the urine.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ascorbic acid 500mg

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a cool dry place. Below 30°C.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

A clear colourless solution filled in 5ml Type-1 Amber coloured glass ampoule. Pack size: 5ml x 10 ampoule.

6.6 Special precautions for disposal <and other handling>

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT

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