Ascorbic Acid Injection, USP

Package inserts are current as of January, 1997. Contact Professional Services,
1-888-744-1414, regarding possible revisions

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DESCRIPTION

Ascorbic acid (vitamin C) is a water-soluble vitamin. It occurs as a white or slightly yellow crystal or powder with a slight acidic taste. It is an antiscorbutic product. On exposure to light, it gradually darkens. In the dry state, it is reasonably stable in air, but in solution it rapidly oxidizes. Ascorbic acid is freely soluble in water; sparingly soluble in alcohol; insoluble in chloroform, in ether, and in benzene. The chemical name of ascorbic acid is L-ascorbic acid. The empirical formula is C6H806, and the molecular weight is 176.13. The structure is as follows:
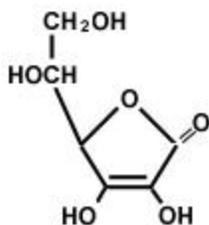
Ascorbic Acid Injection is a sterile solution. Each mL contains: Ascorbic Acid 250 mg and Edetate Disodium 0.025% in Water for Injection qs. Prepared with the aid of Sodium Bicarbonate. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH.

CLINICAL PHARMACOLOGY

In humans, an exogenous source of ascorbic acid is required for collagen formation and tissue repair. Ascorbic acid is reversibly oxidized to dehydroascorbic acid in the body. These two forms of the vitamin are believed to be important in oxidation-reduction reactions. The vitamin is involved in tyrosine metabolism, conversion of folic acid to folinic acid, carbohydrate metabolism, synthesis of lipids and proteins, iron metabolism, resistance to infections, and cellular respiration.

Ascorbic acid deficiency results in scurvy. Collagenous structures are primarily affected, and lesions develop in bones and blood vessels. Administration of ascorbic acid completely reverses the symptoms of ascorbic acid deficiency.

INDICATIONS AND USAGE

Vitamin C is recommended for the prevention and treatment of scurvy. Its parenteral administration is desirable for patients with an acute deficiency or for those whose absorption of orally ingested ascorbic acid is uncertain.

Symptoms of mild deficiency may include faulty bone and tooth development, gingivitis, bleeding gums, and loosened teeth. Febrile states, chronic illness, and infection (pneumonia, whooping cough, tuberculosis, diphtheria, sinusitis, rheumatic fever, etc.) increase the need

for ascorbic acid.

Hemovascular disorders, burns, delayed fracture and wound healing are indications for an increase in the daily intake.

CONTRAINDICATIONS
Contraindicated in those persons who have shown hypersensitivity to any component of this preparation.

WARNINGS
Diabetics, patients prone to recurrent renal calculi, those undergoing stool occult blood tests, and those on sodium-restricted diets or anticoagulant therapy should not take excessive doses of vitamin C over an extended period of time.

PRECAUTIONS

General Precautions
Too-rapid intravenous injection is to be avoided.

Laboratory Tests
Diabetics taking more than 500 mg vitamin C daily may obtain false readings of their urinary glucose test. No exogenous vitamin C should be ingested for 48 to 72 hours before amine-dependent stool occult blood tests are conducted because possible false-negative results may occur.

Drug Interactions
Limited evidence suggests that ascorbic acid may influence the intensity and duration of action of bishydroxycoumarin.

Usage in Pregnancy
Pregnancy Category C.' Animal reproduction studies have not been conducted with Ascorbic Acid Injection. It is also not known whether Ascorbic Acid Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ascorbic Acid Injection should be given to a pregnant woman only if clearly needed.

Nursing Mothers
Caution should be exercised when Ascorbic Acid Injection is administered to a nursing woman.

ADVERSE REACTIONS
Transient mild soreness may occur at the site of intramuscular or subcutaneous injection. Too-rapid intravenous administration of the solution may cause temporary faintness or dizziness.

DOSAGE AND ADMINISTRATION

Ascorbic acid is usually administered orally. When oral administration is not feasible or when malabsorption is suspected, the drug may be administered IM, IV, or subcutaneously. When given parenterally, utilization of the vitamin reportedly is best after IM administration and that is the preferred parenteral route.

For intravenous injection, dilution into a large volume parenteral such as Normal Saline, Water for Injection, or Glucose is recommended to minimize the adverse reactions associated with intravenous injection.

The average protective dose of vitamin C for adults is 70 to 150 mg daily. In the presence of scurvy, doses of 300 mg to 1 g daily are recommended. However, as much as 6 g has been administered parenterally to normal adults without evidence of toxicity.

To enhance wound healing, doses of 300 to 500 mg daily for a week or ten days both preoperatively and postoperatively are generally considered adequate, although considerably larger amounts have been recommended. In the treatment of burns, doses are governed by the extent of tissue injury. For severe burns, daily doses of 1 to 2 g are recommended. In other conditions in which the need for vitamin C is increased, three to five times the daily optimum allowances appear to be adequate.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

HOW SUPPLIED
Ascorbic Acid Injection, USP, 250 mg/mL is available in 2 mL ampules, in cartons of 25.

PROTECT FROM HEAT AND LIGHT. Store at controlled room temperature 15°- 30° C (59°- 86° F).

Pressure may develop within the ampule upon long storage. Precautions should be taken to wrap the container in a protective covering while it is being opened.

CAUTION: Federal law prohibits dispensing without prescription.

Manufactured by:
Steris Laboratories, Inc. Phoenix, Arizona 85043 USA

For:
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St. Louis, MO 63134

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