ASCORBIC ACID

AZCOR-C
250 mg/mL (500 mg/2 mL)
Solution for Injection
(IM/IV/SC)
VITAMIN

℞

FORMULATION:
Each 2 mL Ampoule contains:
Ascorbic Acid BP ..... 500 mg

PRODUCT DESCRIPTION:
AZCOR-C Solution for Injection is a clear colorless solution.

INDICATIONS:
Used in the treatment and prevention of Vitamin C deficiency.

PHARMACOKINETICS:
Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues. Plasma concentrations of ascorbic acid rise as the dose ingested are increased until a plateau is reached with doses of about 90 to 150 mg daily. Body stores of ascorbic acid in health are about 1.5 g although more may be stored at intakes above 200 mg daily. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma. In deficiency states the concentration in leucocytes declines later and at a slower rate, and has been considered to be a better criterion for the evaluation of deficiency than the concentration in plasma.
Ascorbic acid is reversibly oxidised to dehydroascorbic acid; some is metabolised to ascorbate-2-sulfatewhich is inactive, and oxalic acid which are excreted in the urine. Ascorbic acid in excess of the body's needs is also rapidly eliminated unchanged in the urine; this generally occurs with intakes exceeding 100 mg daily. Ascorbic acid crosses the placenta and is distributed
into breast milk. It is removed by haemodialysis.

Human Requirements
A daily dietary intake of about 30 to 100 mg of vitamin C has been recommended for adults. There is, however, wide variation in individual requirements. Humans are unable to form their own ascorbic acid and so a dietary source is necessary. Most dietary ascorbic acid is obtained from fruit and vegetable sources; only small amounts are present in milk and animal tissues. Relatively rich sources include rose hips (rose fruit), black currant, citrus fruits, leafy vegetables, tomatoes, potatoes, and green and red peppers.
Ascorbic acid is readily destroyed during cooking processes. Considerable losses may also occur during storage.
Differing amounts are recommended for infants and children of varying ages, for adult males and females, and for pregnant and lactating women. In the UK the reference nutrient intake (RNI) is 40 mg daily for adult males and females and the estimated average requirement (EAR) is 30 mg daily. In general the amount recommended in the USA for all ages and groups is higher than that set in the UK; the recommended daily allowance (RDA) is 90 mg daily for men and 75 mg daily for women. The RDA is increased in smokers by 35 mg daily. The tolerable upper intake level is 2 g daily. The EAR is 75 mg daily for men and 60 mg daily for women.

DOSAGE AND ADMINISTRATION:
Vitamin C, a water-soluble vitamin, is essential for the synthesis of collagen and intercellular material. Vitamin C deficiency develops when the dietary intake is inadequate. It is rare in adults, but may occur in infants, alcoholics, or the elderly. Deficiency leads to the development of a well-defined syndrome known as scurvy. This is characterised by capillary fragility, bleeding (especially from small blood vessels and the gums), normocytic or macrocytic anaemia, cartilage and bone lesions, and slow healing of wounds. Vitamin C is used in the treatment and prevention of deficiency. It completely reverses symptoms of deficiency. It is usually given orally, the preferred route, as ascorbic acid, and has been given to children in the form of a suitable fruit juice such as orange juice or as black currant or rose hip syrups. Ascorbic acid or sodium ascorbate may be given parenterally, preferably by the intramuscular route, but also by the intravenous or subcutaneous routes. Doses of 25 to 75 mg daily in the prevention of deficiency, and 250 mg or more daily in divided doses for the treatment of deficiency, have been recommended.

ADVERSE EFFECTS AND PRECAUTIONS:
Ascorbic acid is usually well tolerated. Large doses are reported to cause diarrhoea and other gastrointestinal disturbances. It has also been stated that large doses may result in hyperoxaluria and the formation of renal calcium oxalate calculi and ascorbic acid should therefore be given with care to patients with hyperoxaluria. Tolerance may be induced with prolonged use of large doses, resulting in symptoms of deficiency when intake is reduced to normal. Prolonged or excessive use of chewable vitamin C preparations may cause erosion of tooth enamel. Large doses of ascorbic acid have resulted in haemolysis in patients with G6PD deficiency.
Breast Feeding:

Vitamin C is excreted into breast milk and thus supplied to breast-feeding infants. Lactating women in developing countries have significantly lower concentrations of ascorbic acid in their breast milk compared with lactating women in developed countries, and seasonal variation in consumption of foods rich in vitamin C leads to variable amounts of ascorbic acid in breast milk. Supplementation with high-dose ascorbic acid (1 g daily for 10 days) led to significant increases in breast-milk concentrations in both European and African women; however, the overall effect was modest in European women compared with a threefold increase observed in African women. Lower doses of 100 mg daily for 10 days approximately doubled the ascorbic acid breast milk content in the latter, as did supplementation with orange juice 3 or 5 times a week; a significant day-to-day effect was also noted, indicating that the ascorbic acid content of breast milk is regulated.
In a small study involving four different doses of ascorbic acid supplements, women in West Africa showed that increased intake caused an increase in the ascorbate concentration of breast milk, but concentrations approached a plateau at higher intakes; it was concluded that about 100 to 120 mg of vitamin C daily was needed to achieve acceptable plasma and breast-milk ascorbate concentrations in this population.

Effects on the blood:

There are reports of haemolysis in patients with G6PD deficiency after large doses of ascorbic acid either intravenously or in soft drinks. There has also been a report of a patient with paroxysmal nocturnal haemoglobinuria suffering haemolysis after taking large amounts of ascorbic acid in a soft drink. There is concern that the large quantities of vitamin C in feeds for premature neonates may have a pro-oxidant effect, and lead to haemolysis. However, a double-blind study found no increase in erythrocyte destruction or hyperbilirubinaemia in premature neonates receiving vitamin C.

Effects on the kidneys:

Although renal impairment associated with excessive oxalate excretion has been reported with large doses of ascorbic acid. It has been considered that healthy persons can ingest large amounts of ascorbic acid with relatively small increases in oxalate excretion and without an increased risk of oxalate stone formation. A study of vitamin C supplementation with 1 or 2 g given daily for 3 days in calcium stone-forming patients, and 1 g given daily for 3 days in healthy subjects, found that urinary oxalate excretion and the risk of calcium oxalate crystallisation increased significantly in all groups.
A prospective cohort study found that increased vitamin C intake (over 1 g daily) was positively associated with the risk of stone formation; an increased risk was observed even at lower intakes of about 90 to 250 mg daily. The risk was raised for both dietary and supplemental vitamin C intake. However, the relation between vitamin C intake and stone formation had emerged only after the inclusion of dietary potassium in the analysis, with potassium intake positively associated with dietary vitamin C intake, but inversely associated with stone formation. This led the authors to conclude that, while limiting dietary vitamin C intake in men with calcium oxalate nephrolithiasis was unwarranted (because of the high potassium content of vitamin C-rich foods), supplemental vitamin C should be avoided.

REPORTING OF SUSPECTED ADVERSE REACTIONS:

To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.
Protect from light.

AVAILABILITY:

2 mL USP Type I Amber Glass Ampoule (Box of 10's)

FDA Registration Number: DRP-6465
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Manufactured by:
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