

# PRODUCT CHARACTERISTICS(SmPC)

ON[Ascorbic Acid 500mg/5ml] 5ml X 10 Ampoules

## Medicinal product

[Ascorbic Acid Injection 500mg/5ml]

## Quantitative composition

/v

## Form

## Uses

## Indications

Treatment of scurvy, or other conditions requiring vitamin C  
if the deficiency is acute or oral administration is difficult.

## Method of administration

Route: Parenteral

Dose: 200 to 500mg daily for preventative therapy.

For curative purposes, or 30mg daily for protective treatment.

Requirements have been suggested.

## Contraindications and precautions for use

Should be given with care to patients with underlying renal failure due to  
renal oxalate calculi. Tolerance may be induced in patients

Ascorbic Acid have resulted in haemolysis in patients with glucose-6-  
phosphate (G6PD) deficiency.

## Other medicinal products and other forms of interaction

Factors that cause desaturation of ascorbic acid include aspirin, nicotine from  
tobacco, alcohol, oral contraceptives, iron, phenytoin, some anti-  
oxidants, the oestrogen component of oral contraceptives and tetracycline.  
Ascorbic acid may cause the urine to become acidic causing unexpected  
excretion of acidic drugs, thus producing an exaggerated response.  
Ascorbic acid may exhibit decreased reabsorption resulting in a decreased  
response. High doses may reduce the response to oral anticoagulants.  
At concurrent administration of ascorbic acid and fluphenazine  
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 Fertility, pregnancy and lactation**

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**

Large doses may cause gastrointestinal disorders including diarrhoea. Large doses may also result in hyperoxaluria and renal oxalate calculi may form if urine is acidic. Doses of 600mg or more daily have a diuretic action. Stop treatment and treat symptomatically.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

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 gastro-intestinal 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.