

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

LINUS Vitamin C Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ascorbic Acid BP 100%

3 PHARMACEUTICAL FORM

Powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Scurvy and all other manifestations of vitamin C deficiency.

Prophylaxis of scurvy.

Adjunct in the treatment of anaemia, infections, wounds and fractures.

4.2 Posology and method of administration

Adults: As an accompaniment to the treatment of infections, anaemia, wounds and fractures:

200 to 500 mg daily (1/8 to 1/6 teaspoon) in water or a drink such as orange juice or blackcurrant juice, preferably after a meal.

For the treatment of scurvy:

1 g (1/3 teaspoon) two or three times daily in water or a drink such as orange juice or blackcurrant juice, preferably after a meal.

Children: 6 to 12 years: Half the adult dose.
Under 5 years: Quarter of the adult dose.

Elderly: As for the adult dose.

4.3 Contraindications

Renal calcium oxalate calculi.

4.4 Special warnings and precautions for use

Should be given with care to patients with hyperoxaluria.

4.5 Interaction with other medicinal products and other forms of interaction

Ascorbic acid could interfere with the laboratory estimations of blood or urine creatinine, glucose, uric acid, liver enzymes and bilirubin. Ascorbic acid increases the apparent half-life of some drugs undergoing sulphate conjugation but the clinical significance of this is not known.

4.6 Fertility, Pregnancy and lactation

May be used in pregnancy and lactation. Doses greater than 1 gram daily should not be taken because the effect of large doses on the foetus is not known.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Large doses may cause diarrhoea. In some individuals with deficiency of glucose-6-phosphate dehydrogenase, Vitamin C may cause haemolytic anaemia.

4.9 Overdose

Overdose is not serious and no special treatment is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid is essential for the synthesis of collagen and intercellular material. It is involved in the conversion of folic acid to folinic acid, in electron transport processes, and in the healing of wounds, and is believed to be involved in the metabolism of tyrosine.

5.2 Pharmacokinetic properties

Ascorbic Acid is absorbed from the gastro-intestinal tract and widely distributed in the body tissues, the concentration being highest in leucocytes and platelets and lowest in the erythrocytes and plasma.

Any Ascorbic Acid in excess of the body's requirements is rapidly eliminated in the urine accompanied by mild diuresis.

Plasma concentrations fall with increasing age.

Ascorbic Acid is partly metabolised to the sulphate and can modify the transformation of drugs similarly metabolised. Ascorbic-3-sulphate is a metabolite of Ascorbic Acid.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nil.

6.2 Incompatibilities

Not known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.
Keep in well closed containers.
Protect from light and metals.
Keep out of reach of children.

6.5 Nature and contents of container

High density polystyrene containers with polythene lids, or polypropylene containers with polypropylene or polythene lids.

Pack sizes: 60, 100, 250,500, 1000 and 5000 grams.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
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3rd Floor, 1060 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0155

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1972 / 8th February 1999

10 DATE OF REVISION OF THE TEXT

16/01/2015