

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ascorbic Acid Tablets BP 50mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active	mg/tablet
Ascorbic Acid BP	50.0mg

3 PHARMACEUTICAL FORM

Uncoated tablets for oral administration

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The indications for Ascorbic Acid are the treatment of scurvy. Prophylactically in cases where deficiency might be expected to occur.

4.2 Posology and method of administration

Children, Adults, & the elderly:
Two tablets three times a day

Prophylactic dose: One tablet twice daily

4.3 Contraindications

No significant contra-indications

4.4 Special warnings and precautions for use

Use with care in patients with hyperoxaluria. Doses above 600mg daily may have a diuretic effect. Large doses may cause diarrhoea.

4.5 Interaction with other medicinal products and other forms of interaction

May adversely affect the action of warfarin in very high doses.

4.6 Fertility, pregnancy and lactation

Doses greater than 1g daily should not be taken during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

None

4.9 Overdose

Diarrhoea is a symptom of high doses/overdose and in cases showing symptoms discontinue vitamin C

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid is essential for the synthesis of collagen and intercellular material involved in conversion of folic acid to folinic acid.

5.2 Pharmacokinetic properties

Ascorbic acid is well absorbed from the gastro-intestinal tract, and is widely distributed in body tissues. Excess material is readily excreted in the urine.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP, Potato Starch BP, Syrup BP, Colloidal Silicon Dioxide USNE, Talc BP, Stearic Acid BPC

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Tablets should be stored in a cool dry place below 20°C

6.5 Nature and contents of container

The tablets are available in Securitainers or Tampertainers in packs of 100, 500 or 1000 tablets.

Specification for Securitainers and Tampertainers: High density polypropylene containers with low density polyethylene caps.

The tablets are also available in blister packs of 28 tablets.

Specification details of blister packs:

- PVC (rigid, PVdC coated): 286.6 microns \pm 5%
- Aluminium foil (hard tempered): 30 \pm 2 microns
- Primer: 1 \pm 0.4gsm
- Heat seal lacquer: 7 \pm 1.5gsm

6.6 Special precautions for disposal

Always read instructions on the label and the Patient Information Leaflet (PIL) enclosed

Keep all medicines out of the reach of children

Do not use after the expiry date

7 MARKETING AUTHORISATION HOLDER

Noumed Life Sciences Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 44041/0106

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/09/2005

10 DATE OF REVISION OF THE TEXT

20/02/2018