

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) FOR VITAMIN C TABLET.

**VITAMIN C (ASCORBIC ACID ; 100MG) SUBMITTED BY: NALIS
PHARMACEUTICALS LTD**

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1. NAME OF THE MEDICINAL PRODUCT

NALIS VITAMIN C

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each plastic container contains:

Vitamin C 100mg x 1000 Tablets.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Name of product:

Vitamin C (Ascorbic Acid)

Composition: Vitamin C (Ascorbic Acid ; 100 mg)

Dosage form: Tablet

Indications: It is recommended for the treatment of cold, catarrh and scurvy. It promotes healing in wounds and fractures. As a nutritional supplement, regular use build up the immune system.

4.2 Posology and method of administration

Adults and children:

Take a tablet or two of Vitamin C to supplement for loss of vitamin and to boost the immune system.

Method of administration

It is taken orally by mouth with some water.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

4.4.1 Warning:

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.

4.4.2 Precautions:

Usage in Pregnancy

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

Nursing Mothers

Caution should be exercised when Ascorbic Acid (vitamin c) Injection is administered to a nursing woman.

4.5 Interaction with other medicinal products and other forms of interaction

Effect of other medicinal products on Vitamin C (Ascorbic Acid)

Limited evidence suggests that ascorbic acid (vitamin c) may influence the intensity and duration of action of bishydroxycoumarin **Side Effects:**

Ascorbic Acid may cause serious side effects including:

nausea,
vomiting,
heartburn,
stomach cramps, and
Headache

Transient mild soreness may occur at the tongue and lips.

4.6 Fertility, pregnancy and lactation Serves
as a vitamin supplement **4.7 Effects on ability
to drive and use machines** Not
Applicable

4.8 Dosage and Administration

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.

Over Dose:

No information provided.

5. Pharmacological properties

Antioxidant and Anti inflammatory properties

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5.1 Pharmacodynamic properties

In humans, an exogenous source of ascorbic acid (vitamin c) is required for collagen formation and tissue repair. Ascorbic acid (vitamin c) is reversibly oxidized to dehydroascorbic acid (vitamin c) 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..

Pharmacodynamic effect

Mechanism of action

Ascorbic acid (vitamin c) deficiency results in scurvy. Collagenous structures are primarily affected, and lesions develop in bones and blood vessels. Administration of ascorbic acid

(vitamin c) completely reverses the symptoms of ascorbic acid (vitamin c) deficiency.

5.2 Pharmacokinetic properties No information provided.

Distribution:

Not applicable

Biotransformation:

No information provided.

Elimination:

Not applicable

5.3 Preclinical safety data Not applicable

6. Pharmaceutical particulars

Not applicable

6.1 List of excipients

Not applicable

6.2 Incompatibilities None known

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6.3 Shelf life

Three years from the date of manufacture.

Shelf-life after dilution/reconstitution Not applicable.

Shelf-life after first opening

Not applicable

6.4 Special precautions for storage Store below 25°C in a dry place.

6.5 Nature and contents of container

Transparent pet bottle

6.6 Special precautions for disposal and other handling No special requirements.

7. Marketing authorisation holder NALIS PHARMACEUTICAL LIMITED

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8. Marketing authorisation number(s)

N/A

9. Date of first authorisation/renewal of the authorization N/A 10. Date of revision of the text

N/A