NALIS® VITAMIN C SYRUP

(ASCORBIC ACID- 100 mg/5 ml)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1. NAME OF THE DRUG PRODUCT

Nalis® Vitamin C Syrup (Ascorbic Acid- 100 mg/5 ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A yellow-coloured syrup.

Each 5 ml contains:

Ascorbic Acid BP……..**100mg**
Excipients…… qs

3. PHARMACEUTICAL FORM

Oral Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nalis® Vitamin C Syrup is indicated for the prevention and treatment of scurvy in children.
It is essential for the development of bone and teeth, in healing of wounds and reducing inflammations.
It is also indicated for treatment of common cold, catarrh and enhances resistance to infections.

4.2 Posology and method of administration

Three times daily:
Infants 1 months-4 year: 2.5ml to 5ml twice daily.
Children 4-12 years: 5ml to 10ml twice daily
Children 12-18 years: 10ml to 25ml twice daily.

Method of administration
Oral administration

4.3 Contradindications

- **This medicinal product increases gastrointestinal absorption of iron. It should not be used in patients with haemochromatosis or thalassaemia.**
- **This medicinal product should not be used in patients with a pre-disposition to oxalate-urolithiasis.**

4.4 Special warnings and precautions for use

Patients with impaired renal function should be monitored because of the risk of the formation of calcium oxalate calculi.
- **High intakes of vitamin C by patients with an erythrocytic glucose-6-phosphate dehydrogenase deficiency may cause haemolyse. Therefore, exceeding the given dosing recommendations must be avoided in these patients.**
- **At vitamin C doses above 2 g/day, ascorbic acid can interfere with the following laboratory tests: measurement of blood and urinary levels of creatinine and glucose (monitoring of diabetes using glucose oxidase test strips).**
- **This medicinal product contains sorbitol. Its use is not recommended in patients with fructose intolerance (a rare inherited disease).**

- **Because of a mild stimulant effect, it is advisable not to take this medicinal product at the end of the day.**
- **If problems persist after 2 weeks of treatment, get worse, or if other symptoms occur investigations into the cause should be undertaken and the treatment re-assessed.**

4.5 Interaction with other drug products and other forms of interaction

Precautions for use
Concomitant treatment with deferoxamine and high doses of vitamin C may lead to cardiac dysfunction. Monitor cardiac function if this combination is used.

Other combinations to be cautious with
Potential for other medicinal products to affect vitamin C
Aspirin can lower plasma levels of vitamin C by increasing its urinary excretion.
Medicinal products that contain oestrogen, such as oral contraceptives (birth control pills) and hormone replacement therapy, can lower plasma concentrations of vitamin C. Calcitonin increases the rate of vitamin C excretion.
Barbiturates (phenobarbital) may increase vitamin C excretion in the urine.
Potential for vitamin C to affect other medicinal products
At high doses (>1 g/day), vitamin C can decrease the effect of anticoagulants. More frequent monitoring of the INR and a possible dosage adjustment are recommended.
A reduction in indinavir blood levels has been reported following administration of high doses of vitamin C. This should be taken into account in patients being treated with protease inhibitors.
High doses of vitamin C taken together with iron may cause an iron overload due to an enhanced iron reabsorption.
High doses of vitamin C may decrease the urinary excretion of paracetamol, which could increase paracetamol blood levels.
Vitamin C may impair the bioavailability of cyclosporine A, phenothiazines and warfarin, and therefore, may decrease the therapeutic effect of these medicinal products.
Prolonged use of high doses of vitamin C can influence the interaction between disulfiram and alcohol.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development (see section 5.3).
Clinically, analysis of a large number of exposed pregnancies does not indicate any particular malformative or fetotoxic effect of vitamin C. However, no well-controlled studies with ascorbic acid during human pregnancy have been performed.

Breastfeeding
Ascorbic acid/metabolites have been identified in breastfed newborns of a treated mother. There is insufficient information on the effects of ascorbic acid in newborns.

Fertility
According to the data available to date, vitamin C is not expected to have an effect on human fertility.

4.7 Effects on ability to drive and use machines
Not applicable

4.8 Undesirable effects

High doses (above 1 g) can trigger digestive disorders (gastric burning, diarrhoea) or urinary disorders (precipitation of urate, cystine and/or oxalate stones) in some subjects, and may cause haemolysis in individuals with G6PD deficiency.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the responsible agency.

4.9 Overdose

At vitamin C doses above 1 g/day, there is the possibility of:
- digestive disorders (gastric burning, diarrhoea),
- urinary disorders (oxalate, cystine and/or urate stones),
- haemolysis in individuals with G6PD deficiency.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ascorbic acid (vitamin C), ATC code: A11GA01.
Vitamin C is essential to humans. Its components, ascorbic acid and dehydroascorbic acid, form an important redox system.
Ascorbic acid has special functions in this redox interrelationship, as an antioxidant and enzyme cofactor, which plays a crucial role in various hydroxylation reactions. There are several ascorbate- dependent mono- and dioxygenations in various neurotransmitter and hormone formation processes, and ascorbate is also required for the hydroxylation of carnitine. It has been suggested that carnitine deficiency is responsible for the early symptoms of scurvy. Vitamin C has certain biological functions that can influence energy production and thus physical performance. In addition to its role for synthesis of collagen and carnitine, which transports long-chain fatty acids into mitochondria, vitamin C is also needed for synthesis of catecholamines, epinephrine, and norepinephrine.
Ascorbic acid facilitates the transport and uptake of non-heme iron at the mucosa, the reduction of folic acid intermediates, and the synthesis of cortisol. Vitamin C is a potent antioxidant that serves to regenerate vitamin E from its oxidized product.

5.2 Pharmacokinetic properties

Absorption
Ascorbic acid is rapidly absorbed by sodium-dependent active transport from the intestine, although the proportion absorbed decrease with increasing doses.

Distribution
It is present in plasma and is extensively distributed to all cells of the body, with higher levels found in the adrenal glands, pituitary and retina, and lower levels in kidney and muscle tissue. Tissue vitamin C concentrations are higher than that of plasma but saturate before.

Metabolism
Ascorbic acid is readily oxidized to dehydroascorbic acid. Irreversible breakdown yields 2,3-diketogulonic acid (without biological action), which is then oxidised to oxalic and threonic acids.

Excretion
The main route of excretion of ascorbic acid is in urine, but a small percentage is excreted in the faeces. Absorbed excess doses are largely excreted unchanged in urine. The plasma half-life of ascorbic acid in humans is 16 days.

5.3 Preclinical safety data

There are no non-clinical data of relevance to the prescriber which are additional to those already included elsewhere in the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

S/N	Excipient	Specification
1	Ascorbic acid	BP
2	Disodium edetate	BP
3	Sodium CMC	BP
4	Citric acid	BP
5	Propylene Glycol	BP
6	Methyl paraben	BP
7	Propyl paraben	BP
8	Glycerine	BP

9	Ethanol	BP
10	Orange flavour	BP
11	Riboflavin phosphate	BP
12	Sugar	BP
13	Sodium metabisulfite	BP
14	Sodium benzoate	BP
15	Xanthan Gum	BP
16	DM Water to	BP

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place.

6.5 Nature and contents of container

100ml Pet bottles.
60 by 100ml in a carton.

6.6 Special precautions for disposal of used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

NAME:
NALIS PHARMACEUTICALS LTD

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8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S):

A11-0826