FIRST VADIS PHARMACEUTICAL INDUSTRIES LIMITED	
BRAND NAME:	**VADIVIT – C SYRUP**
GENERIC NAME:	**ASCORBIC ACID SYRUP 40MG/5ML**

Product information

Summary of product characteristics

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BRAND NAME:	**VADIVIT – C SYRUP**
GENERIC NAME:	**ASCORBIC ACID SYRUP 40MG/5ML**

1. Name of the product

Vadivit-C syrup

2. Qualitative & Quantitative composition

Each 5 ml contains

Vitamin C 40 mg

3. Pharmaceutical form

Oral Solution

4. Clinical particulars

4.1 Therapeutic indications

Treatment of vitamin C deficiency diseases

4.2 Posology and method of administration

Posology The following doses are generally recommended: Adults are given one effervescent tablet (= 1000 mg of ascorbic acid) daily. The therapy duration depends on the physiological need (e.g. in case of increased physical strain) and on condition associated with vitamin C deficiency (e.g. burns, alcoholism or scurvy). Vitamin C should be administered over the period of the physiological need or until the symptoms abate. The maximum therapeutic dose of 1000 mg (1 tablet/day) should not be exceeded. For patients with renal insufficiency, respectively, medicinal products containing lower doses of ascorbic acid are available.

Paediatric population

This strength is not recommended for children (below 18 years). For children medicinal products containing lower doses of ascorbic acid are available.

Method of administration

The effervescent tablets are dissolved completely in a glass of water. Should there be any residue in the empty glass, then this should be taken with more liquid.

4.3 Contraindications

Vadivit – C should not be used in, oxalate-urolithiasis and iron storage diseases (thalassaemia, haemochromatosis, sideroblastic anaemia). Hypersensitivity to the active substanceor to any of the excipients.

4.4 Special warnings and precautions for use

Due to the intake of high doses of vitamin C (4 g per day) by patients with an erythrocytic glucose-6-phosphate dehydrogenase deficiency, partly serious haemolyses have been observed in single cases. Therefore, exceeding the given dosing recommendations must be avoided. Increased intake of ascorbic acid over a prolonged period may result in an increase in renal clearance of ascorbic acid and deficiency may result, if it is withdrawn. In case of the susceptibility to renal calculi, there is the risk of the formation of calcium oxalate calculi due to the intake of high doses of vitamin C. Patients with recurring formation of renal calculi are recommended not to exceed a daily vitamin-C-uptake of 100 to 200 mg. For patients with extreme or terminal renal insufficiency (patients of dialysis), respectively, a daily vitamin-C-uptake of 50 to 100 mg of vitamin C should not be exceeded, because otherwise, there is the risk of hyperoxalataemia and crystallisations of oxalate in the kidneys. High dose vitamin C therapy should be avoided in patients with underlying renal insufficiency or urinary oxalate should be monitored in patients. Nephrotoxic symptoms can occur in patients with renal failure and patients who concomitantly use medicinal products with negative effect on the renal function, e.g. iron overload due to an enhanced iron reabsorption. See section 4.5. This medicinal product contains 321 mg sodium per dose and has to be taken carefully in patients following salt restricted diet (e. g. hypertensive patients). The administration of gram doses can elevate the ascorbic acid concentration in the urine to such a degree that the measurement of various clinical-chemical parameters (glucose, uric acid, creatinine, inorganic phosphate) is impaired. Likewise, gram doses can lead to false-negative results in the attempted detection of occult blood in the stools. Generally, chemical detection methods which are based on colour reactions can be affected.

4.5 Interaction with other medicinal products and other forms of interaction

Although the following interactions between vitamin C and other drugs have been described, their relevance at the proposed dosage is not documented: Vitamin C in a dosage of 1 g daily increases the bioavailability of oral contraceptives (oestrogens). Corticosteroids increase the oxidation of ascorbic acid. Calcitonin increases the rate of vitamin C consumption. Salicylates inhibit active transportation through the intestine.

4.6 Pregnancy and lactation

Pregnancy

It is not advisable to exceed the given dosage during pregnancy and lactation. There is limited amount of data from the use of high dose vitamin C in pregnant women. It is not clear if vitamin C supplementation in amounts exceeding Dietary Reference Intake recommendations is safe or beneficial.

Breastfeeding

Ascorbic acid is secreted into breast milk and crosses the placental barrier by means of simple diffusion. There is insufficient information on the effects of high dose vitamin C in newborns/ infants. It is not clear if vitamin C supplementation in amounts exceeding Dietary Reference Intake recommendations is safe or beneficial.

Fertility

The effect of large doses on the fetus is not known.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Respiratory and cutaneous hypersensitivity reactions have been observed in isolated cases.

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 via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Not applicable.

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. Vitamin C acts as a cofactor in numerous enzyme systems due to its redox potential (collagen formation, catecholamine synthesis, hydroxylation of steroids, tyrosine and exogenous substances, biosynthesis of carnitin, regeneration of tetrahydrofolic acid and alpha-amidisation of peptides, e.g. ACTH and gastrin). Further, a deficiency of vitamin C affects the immune defence reactions, particularly chemotaxis, complement activation and interferon production. The molecular biological functions of vitamin C have not yet been fully explained. Ascorbic acid improves the resorption of iron salts by reducing ferric ions and by forming iron chelates. It blocks the chain reactions in aqueous body compartments triggered by oxygen radicals. The antioxidative functions produce biochemical interactions in close relation to those of vitamin E, vitamin A and carotenoids. As yet it has not been proven entirely that ascorbic acid causes a reduction of potentially carcinogenic substances in the gastrointestinal tract.

5.2 Pharmacokinetic properties

Ascorbic acid is absorbed in the proximal small intestine in a dose-dependent manner. The bioavailability drops with increasing dosage to 60 - 75% after 1 g, to approx. 40% after 3 g and approx. 16% after 12 g. The portion which is not absorbed is broken down by the large intestinal flora into CO2 and organic acids. The maximal metabolic turnover of 40 to 50 mg/day in healthy adults is reached at plasma concentrations of 0.8 to 1.0 mg/dl. The total daily turnover is about 1 mg/kg BW. Brief plasma concentrations of up to 4.2 mg/dl are achieved about three hours after

applying extremely high oral doses. Under these circumstances ascorbic acid is eliminated in the urine by up to 80%. The half-life constitutes 2.9 hours on average. Renal elimination ensues via glomerular filtration and subsequent reabsorption in the proximal tubule. The upper limits given for healthy adults are 1.34 ± 0.21 mg ascorbic acid/dl plasma in men and 1.46 ± 0.22 mg in women, respectively. The total body content of ascorbic acid is at least 1.5 g following a high dose of about 180 mg daily. Ascorbic acid is concentrated in the pituitary gland, adrenal glands, lenses of the eye and white blood cells.

5.3 Preclinical safety data

None stated

6. Pharmaceutical particulars

6.1 List of excipients

Sodium benzoate, Glycerine, Sucrose, Sodium metabisulphate, Banan Flavour, CMC, Tetrazine yellow

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store between 4°C and 25°C. Protect from light.

6.5 Nature and contents of container

100ml pet bottle.

Cap White PP28 TE CR with EPE/PE/AL/PET Wad

6.6 Special precautions for disposal and other handling

None stated

7. Marketing authorisation holder

First Vadis Pharmaceutical Industries Limited
Plot IN/2 Phase 2 Extension,
Emene Industrial Layout Enugu State.

8. Marketing authorisation number(s)

NAFDAC REG. NO.: 04 – 0823

9. Date of first authorisation/renewal of the authorisation

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10. Date of revision of the text
