1. NAME OF THE MEDICINAL PRODUCT

SOPCEE Tablet (Ascorbic Acid 100mg BP.)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ascorbic acid 100mg BP.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White round convex tablet with inscription

'SOPHIA' on one side and plain on the other side

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sopcee (Vit. C) is used in the prevention and treatment of Vitamin C deficiency. It is used for the prevention and treatment of scurvy. It enhances resistance to infections especially after surgery. Vitamin C is essential for the development of cartilage, bone and teeth for the maintenance of good health in infants and children.

4.2 Posology and method of administration

Adult and children over 6 years

Method of administration

For oral administration only.

Dosage: NOT less than 250mg daily and a maximum of 1000mg daily in divided doses

Therapeutic:

This unit dosage form is unsuitable for children under 6 years.

Elderly:

As the dietary intake of Vit. C may less in the elderly, they have greater risk of presenting with vitamin C deficiency.

4.3 Contraindications:

Vitamin C should not be used in, oxalate-urolithiasis and iron storage diseases (thalassaemia, haemochromatosis, sideroblastic anaemia). Hypersentivity to the active substance or to any of the excipient mentioned below:

Ascorbic Acid should not be given to patient with hyperoxaluria

4.4 Special warnings and precautions for use:

Due to the intake of high doses of vitamin C (4 per day) by patients with an erythrocytic glucose-6-phosphate dehydrogenase deficiency, partly serious haemoyses 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a prolonged period may result in an increase in renal clearance of ascorbic acid and deficiency may result, if it is withdrawn.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 dose of vitamin C. Patients with recurring formation of renal calculi, there is the risk of the formation of calcium oxalate calculi due to 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 200mg. For patients with extreme or terminal renal insufficiency (patients of dialysis), respectively, a daily vitamin–C-uptake of 50 to 100mg of vitamin C should not be exceeded, because otherwise, there is the risk of hyperoxalataemia and crystallizations 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 product 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 does 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. The colorings contained in Dr. Scheffler Vitamin C –orange yellow S (E 110) and azorubine (E 122) – can cause allergic reaction including asthma. Such allergic reactions can occur in particular in persons allergic to acetylsalicylic acid. This medicinal product sorbitol and therefore patients with rare hereditary problems of fructose intolerance should not take this medicine. Paediatric population. This strength is not recommended for children (below 18 years).

Interference with serological testing

Ascorbic acid may interfere with test and assays for urinary glucose, giving false-negative results with methods utilizing glucose oxidase with indicator (e.g. Labstix, Tes-Tape) and false – positive results with neocuproine methods.

Estimation of uric acid by phosphotungstate or uricase with copper reduction and measurement of creatinine in non-deproteinised serum may also be affected

High doses of ascorbic acid may give false – negative reading in faecal occult blood tests.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose – galactose malabsorpition should not take this medicine.

4.5.Interaction with other medicinal products and other forms of interaction

Ascorbic acid increases the renal excretion of amphetamine. The plasma concentration of ascorbate is decreased by smoking and oral contraceptives.

Ascorbic acid increases the absorption of iron.

Concomitant administration of aspirin and ascorbic acid may interfere with absorption of ascorbic acid Renal excretion of salicylate is not affected and does not lead to reduced anti – inflammatory effects of aspirin.

Concomitant administration of aluminum –containing antacids may increase urinary aluminum elimination. Concurrent administration of antacids and ascorbic acid is not recommended, especially in patients with renal insufficiency.

Co-administration with amygdalin (a complementary medicine) can cause cyanide toxicity.

Concurrent administration of ascorbic acid with desferrixamine enhances urinary iron excretion. Cases of cardiomyopathy and congestive heart failure have been reported in patients with idiopathic haemochromatosis and thalassaemias receiving desferrioxamne who were subsequently given ascorbic acid. Ascorbic acid should be used with caution in these patients and cardiacfunction monitored.

Ascorbic acid may interfere with biochemical determinations of creatinine, uric acid and glucose in samples of blood and urine.

4.6.Fertility, pregnancy and lactation

Pregnancy

For ascorbic acid no clinical data on exposed pregnancies are available animal studies do not indicate direct or harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development pregnant women should exercise caution.

Breast – feeding

Ascorbic acid is excreted in breast milk. Though again caution should be exercised, no evidence exists suggesting such excretion is hazardous to the infant.

4.7.Effects on ability to drive and use machines

On the basis of the product's pharmacodynamics profile and reported adverse events, ascorbic acid has no known effect on an individual's ability to drive or operate machinery.

4.8.Undesirable effects

Nervous system disorders; headache.

Vascular disorder: flushing.

Gastrointestinal disorder: nausea, vomiting and stomach cramps. Large doses of ascorbic acid may cause diarrhea.

Skin and subcutaneous tissue disorders: redness of skin.

Renal and urinary disorders: patients known to be at risk of hyperoxaluria should not ingest ascorbic acid doses exceeding 1g daily as there may be increased urinary oxalate excretion. However, such risk has not been demonstrated in normal, non-hyperoxaluric individuals. Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase.

Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600mg daily have a diuretic effect.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allow 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 at: www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple App Store.

4.9.Overdose

Symptoms

At doses of over 3g per day unabsorbed ascorbic acid is mainly excreted unmetabolised in the faeces. Absorbed ascorbic acid additional to the body's needs is rapidly eliminated. Large doses of ascorbic acid may cause diarrhea and the formation of renal oxalate calculi. Symptomatic treatment may be required Ascorbic acid may cause acidosis or haemolytic anaemia in certain individuals with a deficiency of glucose 6-phosphate dehydrogenase. Renal failure can occur with massive ascorbic acid over dosage.

Management

Gastric lavage may be given if ingestion is recent otherwise general supportive measure should be employed as required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins – Ascorbic acid.

ATC code: A11GA01

Ascorbic acid, coupled with dehydroascorbic acid to which it is reversibly oxidized, has a variety of functions in cellular oxidation processes. Ascorbic acid is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus in collagen formation e.g. For intercellular substances and during wound healing); the formation of the neurotransmitters 5 hydroxytryptamine from trptophan and noradrenaline from dopamine, and he biosynthesis of camitine from lysine and methionine. Ascorbic acid appears to have an important role in metal ion metabolism, including the gastrointestinal absorption of iron and its transport between plasma and storage organs. There is evidence that ascorbic acid is required for normal leucocyte functions and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system. Deficiency of ascorbic acid leads to scurvy, which may be manifested by weakness, fatigue, dyspnea, aching bones, perifollicular hyperkeratosis, petechial and ecchymosis, swelling and bleeding of the gums, hypochromic anaemia and other haematopoietic disorders, together with reduced resistance to infections and impaired wound healing.

5.2 Pharmacokinetic properties

Absorption

Ascorbic acid is well absorbed in the proximal small intestine of the gastrointestinal

Distribution

Ascorbic acid is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma.

Elimination

Ascorbic acid additional to the body's needs, generally amounts above 200mg daily, is rapidly eliminated; unmetabolised ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

5.3 Preclinical safety data

There are no other preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients	Purpose
Magnesium stearate	Lubricant
Talc	Lubricant
Lactose Monohydrate	Bulking agent
Maize Starch	Binder
Sodium MetabiSulphite	Preservative
Sodium Edtate	preservative
Sugar	sweetening agent

6.2 Incompatibilities

None

6.3 Shelf life

Plastic Containers: 3 years

Blister packs: 3 years

6.4 Special Precautions for storage

Plastic Container: keep the container tightly closed to protect from light and moisture.

Blister Packs: Keep the blisters shrink wrapped inside a polythene Nylon to protect from light and moisture.

6.5 Nature and content of container

Opaque plastic container (securitainer) fitted with plastic cap. The opaque plastic containers composed of either high density polypropylene or high density polyethene with a tamper – evident or child – resistant temper – evident closure composed of either high density polyethene with a packaging polyethene nylon containing the vit.C. tablets.

Blister packs: PVC/PVDC with printed aluminum foils.

Pack sizes: 100's 1000's in plastic containers
30 X 10 sachet/ Box

6.6 Special precautions for disposed and handling:

No special instruction

7 Marketing authorization holder

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8 Marketing authorization Number:

NAFDAC REG NO:- A – 11 – 100420

9 Date of First authorization

25th August 2022

10 Date OF Revision/RENEWAL

24TH AUGUST 2027