1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME: Vitamin C 100 mg Tablets BP

BRAND NAME: Limcee 100

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:
Ascorbic Acid……...…….100 mg
Excipients……...q.s

For complete list of excipients refer section 6.1.

3. *PHARMACEUTICAL FORM:*

Chewable Tablet

Orange circular concave tablet with one side break-line and other side embossed with SVNL

4. *CLINICAL PARTICULARS*

4.1 Therapeutic Indication:

Vitamin C is recommended for the prevention and treatment of scurvy. Its parenteral administration is desirable for patients with an acute deficiency or for those whose absorption of orally ingested ascorbic acid (vitamin c) is uncertain.

Symptoms of mild deficiency may include faulty bone and tooth development, gingivitis, bleeding gums, and loosened teeth. Febrile states, chronic illness, and infection (pneumonia, whooping cough, tuberculosis, diphtheria, sinusitis, rheumatic fever, etc.) increase the need for ascorbic acid (vitamin c) .

Hemovascular disorders, burns, delayed fracture and wound healing are indications for an increase in the daily intake.

4.2 Posology and method of administration:

Adults and children over 6 years:

Prophylactic: 25 – 75 mg daily.

Note: This unit dosage form is unsuitable for prophylactic use.

Therapeutic: Not less than 250mg daily in divided doses. Maximum of 1000mg daily.

Children under 6 years:

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

Elderly: As for other adults. As the dietary intake of vitamin C may be less in the elderly, they have greater risk of presenting with vitamin C deficiency.

Method of administration: Oral.

4.3 Contraindications:

Hypersensitivity to the active substance or to any other of the tablet ingredients listed. Ascorbic acid should not be given to patients with hyperoxaluria.

4.4 Special warning and precautions for use

Increased intake of ascorbic acid over a prolonged period may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).

Interference with serological testing

Ascorbic acid may interfere with tests 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.

4.5 Drug Interactions

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 aluminium-containing antacids may increase urinary aluminium 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 desferrioxamine enhances urinary iron excretion. Cases of cardiomyopathy and congestive heart failure have been reported in patients with idiopathic haemochromatosis and thalassaemias receiving desferrioxamine who were subsequently given ascorbic acid. Ascorbic acid should be used with caution in these patients and cardiac function monitored.

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

4.6 Pregnancy & Lactation

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.

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

4.8 Adverse Effects

Nervous system disorders: headache.

Vascular disorders: flushing.

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

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-hyper oxaluric 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 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 at: www.mhra.gov.uk/yellowcard or search for 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 unmetabolized in the faeces. Absorbed ascorbic acid additional to the body's needs is rapidly eliminated. Large doses of ascorbic acid may cause diarrhoea 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 overdosage.

Management

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

5. *PHARMACOLOGICAL PROPERTIES:*

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Vitamins (Vitamin C)

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 collagen formation e.g. for intercellular substances and during wound healing); the formation of the neurotransmitters 5-hydroxytryptamine from tryptophan and noradrenaline from dopamine, and the biosynthesis of carnitine 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, dyspnoea, aching bones, perifollicular hyperkeratosis, petechia 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 from the gastrointestinal tract.

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; unmetabolized 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:

None

6. *PHARMACEUTICAL PARTICULARS*

6.1 List of excipients

Vitamin C 100 mg Tablets BP

List of Excipients:

- Maize starch
- Lactose
- Gelatin
- Propyl paraben
- Methyl paraben

- Sunset yellow supra
- Aerosil
- Magnesium stearate
- Talcum
- Sweet orange dry powder
- Aspartame

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Store in a cool and dry place below 30^0 C.

6.5 Nature and contents of container

100 tablets in a LD bag packed in HDPE jar along with an insert.

6.6 Special precautions for disposal and other handling

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

7. *APPLICANT*

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 6, New Makun City,
Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu.
Ogun State,
NIGERIA

8. *WHO PREQUALIFICATION REFERENCE NUMBER*
Not applicable

9. *DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION*
Not applicable

10. ***DATE OF REVISION OF THE TEXT***

Not applicable