ZUGOCEE VITAMIN C SYRUP

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF MEDICINAL PRODUCT

ZUGOCEE VITAMIN C SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE ACTIVE INGREDIENT

Each 5ml contains:

Ascorbic acid B.P. 100mg

For excipients see 6.1

3. PHARMACEUTICAL FORM

Liquid Syrup

Orange viscous liquid syrup presented in 100ml pet bottle with customized 'VISKO' ROPP screw cap packed in an outer secondary pack, shrink-wrapped and shipped in a tertiary carton.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

ZUGOCEE syrup is used for the prevention and treatment of Scurvy

ZUGOCEE syrup enhances the Immune system thereby reducing susceptibility to infections like cold, catarrh, mouth sores and promotes antioxidant activity.

ZUGOCEE syrup is useful for the development of bone, teeth and healing of wounds, injuries or inflammations

4.2 Posology and Method of Administration

Adults (above 12 years): 5ml-10ml 3 times daily.

Children:1-5 years: 2.5ml 3 times daily

6-12 years: 5ml 3 times daily

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Ascorbic acid should not be given to patients with hyperoxaluria.

4.4 Special Warnings 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may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).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-deproteinized serum may also be affected.

High doses of ascorbic acid may give false-negative reading in fecal occult blood tests.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose- galactose malabsorption 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 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 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 **Effect on ability to Drive and use Machine**

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 **Undesirable 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 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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 **Overdose**

Symptoms and signs

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 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.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 **Pharmacodynamic Properties**

Ascorbic acid is reversibly oxidized to dehydroascorbic acid in the body which 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 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.

Metabolism and 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 SmPC.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Sugar
- Sodium benzoate
- Orange Flavor
- Sucralose
- Citric acid
- Sodium Metabisulphite
- Sodium EDTA
- Xanthan Gum
- Sunset yellow

6.2 Incompatibilities

None.

6.3 Shelf Life

2years (24months)

6.4 Special Precaution for Storage

Store below 30°C, protect from sunlight.

Keep out of reach and sight of children

6.5 Nature and Content of Container and Special equipment for use, Administration or Implantation

Primary pack: 100ml amber colored PET bottle with a customized 'VISKO' ROPP cap

Equipment for administration: Transparent 10ml measuring cup

Secondary pack: customized outer pack

Shipping cartons.

6.6 **Special Precaution for Disposal and other Handling**

None.

7.0 APPLICANT/ MANUFACTURER

Manufactured in Nigeria by

Jehyson Healthcare Limited

Jehyson Crescent

78 Lagos Expressway,

Apomu town Arigbajo

Ewekoro L.G.A, Ogun State

Marketed by

ZUGOMED PHARMACEUTICALS LIMITED