SUMMARY OF PRODUCT CHARACTERIZATION (SMPC) FOR UCGOD VITAMIN C SYRUP

1. Name of the medicinal product
UCGOD Vitamin C Syrup

2. Qualitative and quantitative composition
Each 5ml contains
100mg of Ascorbic acid BP

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Syrup.
An orange-coloured low viscous syrup with orange taste.

4. Clinical particulars
4.1 Therapeutic indications
Vitamin C deficiency
Treatment and prevention of scurvy

4.2 Posology and method of administration
Posology

Children
1 – 6 years ----------2.5ml (1-2 times daily)
6 -11 years----------5ml (1-2 times daily)

Adult
10ml (1-2 times daily)

Method of administration
For oral administration.

4.3 Contraindications
Ascorbic acid should not be given to patients with hyperoxaluria.
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

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period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. (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 utilising glucose oxidase with indicator (e.g. Labstix, Testape) and false- positive results with neocuproin 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 readings in faecal occult blood tests.

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 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 pharmacodynamic profile and reported adverse events, ascorbic acid has no known effect on an individual's ability to drive or operate machinery.

1.8 Undesirable effects

Nervous system disorders: headache. Vascular disorders: flushing

Gastrointestinal disturbances: 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.

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.

Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase.

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.

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 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Vitamins – Ascorbic acid (**vitamin C**)

ATC code: A11GA01

Ascorbic acid, a water-soluble vitamin, is essential for formation of collagen and intercellular material, and therefore necessary for the development of cartilage, bone, teeth and for the healing of wounds. It is also essential for the conversion from folic acid to folinic acid, facilitates iron absorption from the gastro-intestinal tract and influences haemoglobin formation and erythrocyte maturation.

5.2 Pharmacokinetic properties

Distribution - widely distributed in body tissues with about 25% bound to plasma proteins. Large amounts are present in leucocytes and platelets. Ascorbic acid crosses the placenta.

Metabolism - readily oxidised to dehydroascorbic acid where some is metabolised to oxalic acid and the inactive ascorbate - 2 - sulphate. Metabolic turnover appears to be greater in females than males.

Excretion - large doses are rapidly excreted in the urine when in excess of the requirements of the body and after an intravenous dose, about 40% is excreted in 8 hours, which is increased to about 70% after tissue saturation. The amount of unchanged drug is dose dependent; in women the excretion of ascorbic acid

appears to vary with the stage of the menstrual cycle and it is decreased when taking oral contraceptives.

Ascorbic acid is excreted in breast milk.
Oxalic acid and ascorbate - 2 - sulphate are excreted in the urine.

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. Pharmaceutical particulars

6.1 List of excipients

Granulated sugar
Methyl paraben
Propyl paraben
Sodium metabisulphite
Propylene glycol
Sorbitol
Sodium benzoate
EDTA
Orange flavor
Sucralose

6.2 Incompatibilities

None.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Keep the container tightly closed to protect from light, moisture and store below 30°C.

6.5 Nature and contents of container
An amber colour pet bottles capped with Alu cap.

Pack sizes 100ml.

6.6 Special precautions for disposal and other handling
No special instructions.

7. Marketing authorisation holder

UCGOD Pharmaceutical Limited

6, Oba T.T. Dada Avenue, Dental Bus stop

Along Idiroko Road, Ota Ogun State Nigeria.

Manufactured by

Daily Sun Pharmaceutical company limited

Plot 3 & 4 Tomori industrial

Estate off Idriko road Ota Ogun State

Nigeria.