SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Vitamin C 100 mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ascorbic Acid 100 mg.

Excipients with known effect:

Each tablet contains lactose, aspartame (a source of phenylalanine), sunset yellow and sodium metabisulphite.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

Round, orange tablet, scored on one side and imprinted with “CDL” on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of Vitamin C deficiency, including the treatment and prevention of scurvy.

4.2 Posology and method of administration

Posology

Adults and children over 4 years

Treatment requires not less than 250 mg daily, administered in divided doses.

Maximum daily dose: adults and children over 12 years, 1000 mg; children 4–11 years, 500 mg.

Elderly

As for adults.

Method of administration

Oral use. The tablet should be swallowed with water.

4.3 Contraindications

Hypersensitivity to ascorbic acid 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

Prolonged increased intake of ascorbic acid may increase renal clearance of ascorbic acid, and deficiency may occur if high intake is reduced or withdrawn rapidly.

Ascorbic acid may interfere with laboratory tests, including urinary glucose testing and some methods used for estimation of uric acid and creatinine. High doses may also cause false-negative results in faecal occult blood tests.

Patients known to be at risk of hyperoxaluria should use high doses with caution because increased urinary oxalate excretion may occur.

Ascorbic acid has been associated with haemolytic anaemia in some individuals with glucose-6-phosphate dehydrogenase deficiency.

The product contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The product contains aspartame, a source of phenylalanine, and should therefore be used with caution in patients with phenylketonuria.

The product contains sodium metabisulphite and may rarely cause severe hypersensitivity reactions and bronchospasm in susceptible individuals.

The product contains sunset yellow, which may cause allergic-type reactions in susceptible individuals.

4.5 Interaction with other medicinal products and other forms of interaction

Ascorbic acid may reduce the absorption of amphetamines.

Ascorbic acid may increase oral absorption of iron.

Concurrent administration with desferrioxamine enhances urinary iron excretion; cardiovascular function should be monitored because of a possible increase in cardiovascular adverse effects.

Aspirin and ascorbic acid may interfere with absorption of ascorbic acid.

Concomitant administration with aluminium-containing antacids may increase urinary aluminium elimination; concurrent administration is not recommended, particularly in patients with renal insufficiency.

Co-administration with amygdalin may cause cyanide toxicity.

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

4.6 Fertility, pregnancy and lactation

Pregnancy

Available animal data do not indicate direct or harmful effects on pregnancy, embryonal/foetal development, parturition or postnatal development. Pregnant women should nevertheless exercise caution.

Breast-feeding

Ascorbic acid is excreted in breast milk. No evidence indicates that this is hazardous to the breast-fed infant; caution should nevertheless be exercised.

Fertility

No clinical fertility data are available.

4.7 Effects on ability to drive and use machines

Ascorbic acid has no known effect on the ability to drive or use machines.

4.8 Undesirable effects

Large doses may cause gastrointestinal effects, particularly diarrhoea.

Renal and urinary disorders: increased urinary oxalate excretion and renal oxalate calculi may occur, particularly with high doses and in susceptible patients.

Blood and lymphatic system disorders: haemolytic anaemia may occur in certain individuals with glucose-6-phosphate dehydrogenase deficiency.

Other effects associated with prolonged increased intake include increased renal clearance and a possible deficiency following abrupt reduction or withdrawal.

Suspected adverse reactions should be reported through the applicable national pharmacovigilance reporting system.

4.9 Overdose

At doses above approximately 3 g/day, unabsorbed ascorbic acid is mainly excreted unchanged in the faeces. Excess absorbed ascorbic acid is rapidly eliminated.

Large doses may cause diarrhoea and renal oxalate calculi. Massive overdose may be associated with acidosis, haemolytic anaemia in susceptible patients and renal failure.

Management is supportive and symptomatic, with appropriate clinical assessment and monitoring.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins; ascorbic acid (vitamin C), plain. ATC code: A11GA01.

Ascorbic acid is an essential water-soluble vitamin involved in collagen synthesis and several cellular hydroxylation and oxidation processes. It contributes to conversion of folic acid to folinic acid, formation of hydroxyproline and carnitine, neurotransmitter synthesis, iron absorption and transport, normal leukocyte function and other metabolic processes.

Vitamin C deficiency causes scurvy, which may present with fatigue, weakness, bleeding and swelling of the gums, impaired wound healing, petechiae/ecchymoses, bone pain and anaemia.

5.2 Pharmacokinetic properties

Absorption: Ascorbic acid is well absorbed from the gastrointestinal tract.

Distribution: It is widely distributed throughout body tissues, with higher concentrations in leukocytes and platelets than in erythrocytes and plasma. Normal body stores are approximately 1.5 g.

Elimination: Amounts exceeding physiological requirements are rapidly eliminated. Unmetabolised vitamin C and inactive metabolites are principally excreted in urine. Urinary excretion of unchanged ascorbic acid is dose dependent and may be accompanied by mild diuresis.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber additional to those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn starch

Lactose

Methyl parahydroxybenzoate (Methyl paraben)

Propyl parahydroxybenzoate (Propyl paraben)

Gelatin

Sunset yellow

Colloidal anhydrous silica (Aerosil)

Aspartame

Orange flavour

Sodium metabisulphite

Talc

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C. Store in a cool dry place.

6.5 Nature and contents of container

The tablets are sealed in polyethylene bags and packed in jars.

The jars are then packed into an outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

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

7. APPLICANT / HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Cardinal Drugs Limited

14, Ajoke Osho Street, New Oko-Oba, Agege, Lagos, Nigeria.

8. DRUG PRODUCT MANUFACTURER

Cardinal Drugs Limited

14, Ajoke Osho Street, New Oko-Oba, Agege, Lagos, Nigeria.

9. NAFDAC REGISTRATION NUMBER(S)

04-6555

10. DATE OF REVISION OF THE TEXT

September 2026