SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ascorbic Acid 200mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200mg of Ascorbic Acid

Excipients with known effect:
Each tablet contains 18.224 mg lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

White to light yellow, circular flat faced beveled edge uncoated tablets debossed with "V & 200" separated by breakline on one side and plain on other side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The tablets have diameter of 9.0 mm and thickness 3.20 mm.

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: Not less than 250 mg daily in divided doses.

Maximum daily doses:
Adults and children over 12 years, 1000 mg.
Children 4 – 11 years, 500 mg.

The elderly:
As for adults. As the dietary intake of vitamin C may be less in the elderly, they are at greater risk of being deficient in this vitamin.

Method of administration

For oral administration.

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

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may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).

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, Tes-tape) and false positive results with neocuproin methods.
Estimation of uric acid by phosphotungstate or by 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.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, glucose-galactose malabsorption should not take this medicine as it contains lactose.

4.5 Interaction with other medicinal products and other forms of interaction

Ascorbic acid may reduce the absorption of amphetamines.

Ascorbic acid may increase the oral absorption of iron.

Concurrent administration of ascorbic acid with desferrioxamine enhances urinary iron excretion. Ascorbic Acid may increase the risk of cardiovascular adverse effects when given with desferrioxamine. Ascorbic acid should be used with caution in patients receiving desferrioxamine and cardiac function should be monitored.

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.

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.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Large doses of ascorbic acid may cause diarrhoea.

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

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 the intake is reduced or withdrawn rapidly. Doses of more than 600mg 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
At doses of over 3 grams per day unabsorbed ascorbic acid is chiefly 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
General supportive measures should be employed as required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins

ATC Code: A11G A01 – Ascorbic Acid (Vit C), Plain

Ascorbic acid is essential for the synthesis of collagen and intercellular material involved in conversion of folic acid to folinic acid.

Ascorbic acid coupled with dehydroascorbic acid to which it is reversibly oxidised, has a variety of functions in cellular oxidation processes. Vitamin C is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus in collagen formation e.g. for intercellular substances 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. Vitamin C 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 also evidence that vitamin C is required for normal leukocyte function and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system.

Deficiency in vitamin C leads to scurvy, which may be manifested by weakness, fatigue, dyspnoea, aching bones, perifollicular hyperkeratoses, petechiae and ecchymoses, swelling and bleeding of gums, hypochromic anaemia and other haemopoietic disorders, together with reduced resistance to infection and impaired wound healing.

5.2 Pharmacokinetic properties

Absorption
Ascorbic acid is well absorbed from the gastro-intestinal tract.

Distribution
Ascorbic acid is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5 grams. The concentration is higher in leukocytes 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 vitamin C 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 preclinical data of relevance to the prescriber which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Microcrystalline Cellulose
Colloidal Anhydrous Silica
Talc
Stearic Acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

HDPE containers: 36 Months
Blister packs: 36 Months

HDPE containers: Discard 100 days after first opening the container.

6.4 Special precautions for storage

HDPE containers: This medicinal product does not require any special temperature storage conditions. Keep the container tightly closed. Store in the original package to protect from moisture.

Blister packs: This medicinal product does not require any special temperature storage conditions. Store in the original package to protect from moisture.

6.5 Nature and contents of container

These tablets are available in white opaque HDPE bottle having white polypropylene child resistant cap of 100 tablets and aluminium-PVC/PVDC white opaque blister of 28 tablets.

6.6 Special precautions for disposal

No special requirements. Any unused product should be disposed in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Flamingo Pharma UK Ltd.
First Floor, Kirkland House,
11-15 Peterborough Road,
Harrow, Middlesex,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 43461/0045

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10 DATE OF REVISION OF THE TEXT

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