SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ascorbic Acid 50mg Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ascorbic Acid 50mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablet.

White, uncoated bi-convex tablets with tablet markings “50”.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of scurvy.

Prophylactically in cases where deficiency might be expected to occur.

4.2 Posology and method of administration

For oral administration.

Adults, the elderly and children:

For the treatment of scurvy: 2 tablets three times a day.

For prophylactic use: 1 tablet twice a day.

4.3 Contraindications

Hypersensitivity to ascorbic acid or any of the other ingredients.

Ascorbic acid supplements 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may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).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
Vitamin C 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 by uricase with copper reduction and measurement of creatinine in non-deproteinised serum may also be affected.

High doses of vitamin C may give false negative readings in faecal occult blood tests.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucosegalactose malabsorption should not take this medicine.

Patients with rare hereditary problems of fructose or galactose intolerance, the LAPP lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine as it contains lactose and sucrose.

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.
Large doses of ascorbic acid may cause acidification of the urine which could alter the rate of renal excretion of some drugs.

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.

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.

4.7 Effects on ability to drive and use machines

None Known.

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.

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 oxylate calculi. Symptomatic treatment may be required.

Ascorbic acid may cause acidosis or haemolytic anaemia in certain individuals with a deficiency of glucose 6-phospahte 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 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins Ascorbic Acid (Vit C), Plain ATC code: A11G A01

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

No data of relevance which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose

Potato Starch

Syrup

Talc

Stearic Acid

Colloidal Anhydrous Silica

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed. Store in the original container

6.5 Nature and contents of container

Polypropylene containers with low density polyethylene caps of 28, 100, 500 & 1000 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Kent Pharma UK Limited
2nd Floor, Connect 38, 1 Dover Place,
Ashford, Kent, England, TN23 1FB.

8 MARKETING AUTHORISATION NUMBER(S)

PL 51463/0135

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/10/2000 / 09/01/2007

10 DATE OF REVISION OF THE TEXT

10/11/2025