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ASCORVIT CHEWABLE TABLETS

ASCORBIC ACID (VITAMIN C) 100mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. NAME OF THE MEDICINAL PRODUCT

ASCORBIC ACID 100mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains Ascorbic Acid 100mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

Orange tablet with "ASCORVIT" marked on one side and "SAM" marked on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Ascorbic acid indicated in the treatment of cold and associated symptoms.
It enhances resistance to infections especially after surgery and helps in the formation of red blood cell.

4.2 Posology and method of administration.

Posology

Adults and children over 6 years:

Prophylactic: 25 – 75 mg daily.

Note: This unit dosage form is unsuitable for prophylactic use.

Therapeutic: Not less than 250mg daily in divided doses. Maximum of 1000mg daily

Children under 6 years:

This unit dosage form is unsuitable for children under 6 years.

Elderly: As for other adults. As the dietary intake of vitamin C may be less in the elderly, they have greater risk of presenting with vitamin C deficiency.

Method of Administration

It is administered orally

4.3 Contraindications

Ascorbic acid should not be given to patients with hyperoxaluria.

4.4 Special warnings and precaution 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.

- Estimation of uric acid by phosphotungstic acid test 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 reading in faecal 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 product 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 the 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 effect.

Nervous system disorders: headache.

Vascular disorders: flushing.

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 individual’s 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.

4.9 Overdose.

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.

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.

Ascorbic acid, coupled with dehydroascorbic acid to which it is reversibly oxidised, 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.

Metabolism

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.

Excretion

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.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn Starch
Lactose
Gelatine
Methyl Paraben
Propyl Paraben
Aspartame
Sod. Meta bi-sulphite
Magnesium Stearate
Aerosil

Sunset yellow

Orange Flavour

Purified Talc

6.2 Incompatibilities

Unknown

6.3 Shelf-life

24 Months from the date of manufacture

6.4 Special precautions for storage

Protect from heat and moisture and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Packed into a polythene seal bag and put into a500cc printed plastic securi-container.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

04 – 5918.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 25th February 2020

10. DATE OF REVISION OF THE TEXT

6th January, 2024