

SPMC ASCORBIC ACID TABLETS BP 100mg

PRESENTATION:

Ascorbic Acid Tablets BP 100mg; Packs of 1000 tablets

Each White, circular, flat beveled tablets of 8.5 mm diameter with "SPC" or "SPMC" letters on one side and score mark on the reverse contains 100mg of Ascorbic Acid BP.

MECHANISM OF ACTION:

Ascorbic acid, a water-soluble vitamin, acts as a cofactor and antioxidant. It is essential for tissue repair and formation of collagen and intercellular materials. Additionally, it is involved in conversion of folic acid to folinic acid, synthesis of lipids and proteins, carbohydrate metabolism, iron absorption and storage, and cellular respiration.

INDICATIONS AND DOSE

<u>Prevention of scurvy</u> Adult: 25–75 mg daily <u>Treatment of scurvy</u> Adult: Not less than 250mg daily in divided doses

CAUTION: CAUTIONS, FURTHER INFORMATION

Iron overload Ascorbic acid should not be given to patients with cardiac dysfunction.

In patients with normal cardiac function ascorbic acid should be introduced 1 month after starting desferrioxamine. Periodic assessment of haematologic, hepatic, and renal function; check for helminth ova in faeces within 3-4 wks. Following the initial therapy.

PRESCRIBING AND DISPENSING INFORMATION:

It is rarely necessary to prescribe more than 100mg daily except early in the treatment of scurvy.

CONTRAINDICATION:

Hypersensitivity to the active substance. Ascorbic acid should not be given to patients with hyperoxaluria.

FOOD INTERACTION:

Induced tissue desaturation with alcohol.

SIDE EFFECTS:

GI disturbances (e.g. diarrhoea, nausea, vomiting, abdominal cramps, transient colic, and flatulent distention), heartburn, fatigue, flushing, headache, insomnia, sleepiness; hyperoxaluria, renal Ca oxalate calculi formation; temporary faintness/dizziness

SPECIAL PRECAUTION:

Patient with hyperoxaluria, G6PD deficiency, DM, haemochromatosis. Renal impairment (e.g. renal failure, renal calculi). 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.

DRUG INTERACTIONS:

Induced tissue desaturation with aspirin, nicotine, Fe, phenytoin, tetracycline estrogen from OCs, and some appetite suppressants and anticonvulsant drugs. Reduced absorption and decreased urinary excretion with aspirin. Reduced serum levels with OCs. May cause unexpected renal tubular reabsorption of acidic drugs and decreased reabsorption of basic drugs. May reduce response to oral anticoagulants. May decrease plasma concentration of fluphenazine. May worsen Fe toxicity to the heart with desferrioxamine.

OVERDOSAGE:

Symptoms 1 -

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.

Management

Gastric lavage may be given if ingestion is recent otherwise general supportive measure should be employed as required.

STORAGE:

Keep tightly closed in a cool & dry place. Protect from light & moisture. Keep all medicines away from children. Store below 30^{0} C.

Manufactured by: State Pharmaceutical Manufacturing Corporation No.11, Sir John Kotalawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka.