1. Name of the medicinal product

VITAMIN C 100MG SYRUP

2. Qualitative and quantitative composition

Vitamin C 100mg Syrup 2.0% w/v

For excipients, see 6.1

3. Pharmaceutical form

Oral Solution

4. Clinical particulars

4.1 Therapeutic indications

The prevention and treatment of scurvy, or other conditions requiring vitamin C supplementation,

4.2 Posology and method of administration

Route of Administration: Oral

Children

100 to 300mg daily for curative purposes, or 30mg daily for protective treatment.

Elderly

No special dosage requirements have been suggested.

4.3 Contraindications

Hyperoxaluria

4.4 Special warnings and precautions for use

Vitamin C 100mg Syrup should be given with care to patients with underlying renal failure due to the risk of formation of renal oxalate calculi. Tolerance may be induced in patients taking high doses.

Large doses of Vitamin C 100mg Syrup have resulted in haemolysis in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs which induce tissue desaturation of Vitamin C 100mg Syrup include aspirin, nicotine from cigarettes, alcohol, several appetite suppressants, iron, phenytoin, some anti-convulsant drugs, the oestrogen component of oral contraceptives and tetracycline. Large doses of Vitamin C 100mg Syrup may cause the urine to become acidic causing unexpected renal tubular reabsorption of acidic drugs, thus producing an exaggerated response. Conversely basic drugs may exhibit decreased reabsorption resulting in a decreased therapeutic effect. Large doses may reduce the response to oral anticoagulants.

It has been reported that concurrent administration of Vitamin C 100mg Syrup and fluphenazine has resulted in decreased fluphenazine plasma concentrations.

Vitamin C 100mg Syrup is a strong reducing agent and interferes with numerous laboratory tests based on oxidation - reduction reactions. Specialised references should be consulted for specific information on laboratory test interferences caused by Vitamin C 100mg Syrup.

Vitamin C 100mg Syrup given in addition to desferrioxamine in patients with iron overload to achieve better iron excretion may worsen iron toxicity, particularly to the heart, early on in the treatment when there is excessive tissue iron. Therefore it is recommended that in patients with normal cardiac function Vitamin C 100mg Syrup should not be given for the first month after starting desferrioxamine. Vitamin C 100mg Syrup should not be given in conjunction with desferrioxamine in patients with cardiac dysfunction.

Aspirin can reduce the absorption of Vitamin C 100mg Syrup by approximately a third and decreases urinary excretion by about half. The clinical importance of this is uncertain.

Patients with kidney failure given aluminium antacids and oral citrate can develop a potentially fatal encephalopathy due to marked rise in blood aluminium levels. There is evidence that vitamin C may interact similarly.

Oral contraceptives lower serum levels of Vitamin C 100mg Syrup.

4.6 Fertility, pregnancy and lactation

Vitamin C 100mg Syrup in doses greater than 1g daily should not be taken during pregnancy since the effect of large doses on the foetus is unknown. Vitamin C 100mg Syrup is excreted in breast milk, but there is no evidence of any hazard.

4.7 Effects on ability to drive and use machines

Vitamin C 100mg Syrup is unlikely to affect the patient's ability to drive or use machinery.

4.8 Undesirable effects

Large doses may cause gastrointestinal disorders including diarrhoea. Large doses may also result in hyperoxaluria and renal oxalate calculi may form if the urine becomes acidic. Doses of 600mg or more daily have a diuretic action. Induced tolerance with prolonged use of large doses can result in symptoms of deficiency when intake is reduced to normal.

4.9 Overdose

Large doses may cause gastrointestinal disorders including diarrhoea. Large doses may also result in hyperoxaluria and renal oxalate calculi may form if urine is acidic. Doses of 600mg or more daily have a diuretic action. Stop treatment and treat symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: A11G A01

Vitamin C 100mg Syrup, a water-soluble vitamin, is essential for formation of collagen and intercellular material, and therefore necessary for the development of cartilage,

bone, teeth and for the healing of wounds. It is also essential for the conversion from folic acid to folinic acid, facilitates iron absorption from the gastro-intestinal tract and influences haemoglobin formation and erythrocyte maturation.

5.2 Pharmacokinetic properties
Distribution - widely distributed in body tissues with about 25% bound to plasma proteins. Large amounts are present in leucocytes and platelets. Vitamin C 100mg Syrup crosses the placenta.

Metabolism - readily oxidised to dehydroVitamin C 100mg Syrup where some is metabolised to oxalic acid and the inactive ascorbate - 2 - sulphate. Metabolic turnover appears to be greater in females than males.

Excretion - large doses are rapidly excreted in the urine when in excess of the requirements of the body and after an intravenous dose, about 40% is excreted in 8 hours, which is increased to about 70% after tissue saturation. The amount of unchanged drug is dose dependent; in women the excretion of Vitamin C 100mg Syrup appears to vary with the stage of the menstrual cycle and it is decreased when taking oral contraceptives.

Vitamin C 100mg Syrup is excreted in breast milk.

Oxalic acid and ascorbate - 2 - sulphate are excreted in the urine.

5.3 Preclinical safety data
None stated

6. Pharmaceutical particulars

6.1 List of excipients
Sodium Bicarbonate

Sodium Metabisulphite

Hydrochloric acid

Water for injections

6.2 Incompatibilities
Incompatible with ferric salts, oxidising agents, and salts of heavy metals, particularly copper.

Injections of Vitamin C 100mg Syrup have been reported to be incompatible with aminophylline, bleomycin sulphate, erythromycin lactobionate, nafcillin sodium, nitrofurantoin sodium, conjugated oestrogens, sodium bicarbonate and sulphafurazole diethanolamine. Occasional incompatibility, depending on pH or concentration, has occurred with chloramphenicol sodium succinate.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store in room temperature of (25°C)

6.5 Nature and contents of container
NA
6.6 Special precautions for disposal and other handling
None stated

7. Marketing authorisation holder

EMZOR PHARMACEUTICAL INDUSTRIES LIMITED

Company contact details

EMZOR PHARMACEUTICAL INDUSTRIES LIMITED

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