SUMMARY OF PRODUCT CHARACTERIZATION (SMPC)

FOR

DR. JESSY VITAMIN C 1000MG CAPLET

1. Name of the medicinal product
Dr. Jessy Vitamin C 1000mg Caplet

2. Qualitative and quantitative composition Each Caplet contains 1000mg of Ascorbic acid.

Excipient(s) with known effect
Lactose monohydrate

For the full list of excipients, see section 6.1.

3. Pharmaceutical form Tablet.
An oblong purple film coated Caplet with “JPLN” inscribed on one side and plain on the other side.

4. Clinical particulars
4.1 Therapeutic indications
he prevention and treatment of scurvy, or other conditions requiring vitamin C supplementation, where the deficiency is acute or oral administration is difficult.

4.2 Posology and method of administration
Posology

Adults and children 12 years and above:

1 Caplet per day taken as a single dose or in divided doses

Accident Victims, male & female adults (especially those bearing children) as well as adults & children above 12 years undergoing surgery or passing through immune system depressed sickness (e.g. viral infections): should take 1 Caplet per day in divided doses

To strengthen and rejuvenate the body immunity during pandemic (viral or bacterial infections) adults 12 years and above, should take 1 Capletin divide doses

Elderly
No special dosage requirements have been suggested.

Method of administration For
oral administration.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Dr. Jessy vitamin C should not be given to patients with hyperoxaluria.

4.4 Special warnings and precautions for use
Drugs which induce tissue desaturation of ascorbic acid 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 ascorbic acid 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 ascorbic acid and fluphenazine has resulted in decreased fluphenazine plasma concentrations.

Ascorbic acid 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 ascorbic acid.

Ascorbic acid 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 ascorbic acid should not be given for the first month after starting desferrioxamine. Ascorbic acid should not be given in conjunction with desferrioxamine in patients with cardiac dysfunction.

Aspirin can reduce the absorption of ascorbic acid 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 ascorbic acid.

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.

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.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

On the basis of the product's pharmacodynamic profile and reported adverse events, Dr. Jessy vitamin C Caplet (ascorbic acid) has no known effect on an individual's ability to drive or operate machinery.

1.8 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

Symptoms

At doses of over 3g per day unabsorbed Dr. Jessy vitamin C Caplet (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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Vitamins – Ascorbic acid (vitamin C)

ATC code: A11GA01

Ascorbic acid, 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 gastrointestinal 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. Ascorbic acid crosses the placenta.

Metabolism - readily oxidised to dehydroascorbic acid 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 ascorbic acid appears to vary with the stage of the menstrual cycle and it is decreased when taking oral contraceptives.

Ascorbic acid is excreted in breast milk.
Oxalic acid and ascorbate - 2 - sulphate are excreted in the urine.

5.3 Preclinical safety data
There are no other preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SMPC

6. Pharmaceutical particulars
6.1 List of excipients
Magnesium Stearate
Sodium Metabisulphite
Methyl Paraben
Propyl Paraben
Aerosil 200

PVP K 30
Talcum
Lactose monohydrate
Maize starch
MCCP

6.2 Incompatibilities None.

6.3 Shelf life
2 years

6.4 Special precautions for storage
Keep the container tightly closed to protect from light, moisture and store below 30°C.

6.5 Nature and contents of container
A white opaque PVC and Alu Foil Blister, packed in inner pack containing leaflet.

Pack sizes 100 Caplets.

6.6 Special precautions for disposal and other handling No
special instructions.

7. Marketing authorisation holder

Jessy Pharmaceutical company Limited

8. Marketing authorisation number(s)

A11-1300