

SUMMARY OF PRODUCT CHARACTERIZATION (SMPC)

FOR

DR. VITAMIN C PLUS ZINC CAPLET

1. Name of the medicinal product

Jessy Vitamin C plus Zinc Caplet

2. Qualitative and quantitative composition Each tablet contains 300mg of Ascorbic acid.

15mg of Elemental Zinc as zinc sulphate monohydrate

Excipient(s) with known effect

Lactose monohydrate

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet.

A round purple film coated Caplet with “Jessy” inscribed on one side and a dividing line on the other side.

4. Clinical particulars

4.1 Therapeutic indications

Wade off infections, fights common cold, hastens healing of wounds maintains healthy tendons, cartilages, bones skin blood vessels as well support body immunity.

4.2 Posology and method of administration

Posology

Adults and children 12 years and above:

1-4 tablets 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 2-4 tablets 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 2-4 tablets in divide doses

In case of a surge during pandemic and those already down with the infection, maximum of 6 tablets in 2 or 3 divided doses

Children 6-12 years: half to two tablets per day

Children below 6 years: seek doctors opinion before using

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.

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

4.4 Special warnings and precautions for use

Jessy vitamin C plus zinc tablet must not be used as a substitute for a balance diet and healthy life style.

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may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).

Accumulation of zinc may occur in cases of renal failure.

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.

Zinc may inhibit the absorption of copper

The absorption of zinc may be reduced by calcium salts.

Concomitant administration of aspirin and ascorbic acid may interfere with absorption of vitamin c. Renal excretion of salicylate is not affected and does not lead to reduced anti-inflammatory effects of aspirin.

Zinc may reduce the absorption of concurrently administered tetracyclines, also the absorption of zinc may be reduced by tetracyclines; when both are being given an interval of at least three hours should be allowed.

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.

The absorption of zinc may be reduced by penicillamine, also the absorption of penicillamine may be reduced by zinc.

4.6 Fertility, pregnancy and lactation

Pregnancy

For Jessy vitamin C plus zinc tablet (ascorbic acid & zinc) 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

Jessy vitamin C plus zinc tablet (ascorbic acid & zinc) 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

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

1.8 Undesirable effects

Zinc salts may cause abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation and gastritis. There have also been cases of irritability, headache and lethargy observed.

Ascorbic acid may 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.
- 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 individuals deficient of glucose-6-phosphate dehydrogenase.

4.9 Overdose

Symptoms

At doses of over 3g per day unabsorbed Jessy vitamin C plus zinc tablet (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.

Zinc is corrosive in overdosage. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by perforation may occur. Gastric lavage and emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as sodium calcium edetate may be useful.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Vitamins – Ascorbic acid (vitamin C)

Pharmacotherapeutic Group: Mineral Supplement (Zinc)

ATC code: A11GA01/A12CB01

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.

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

5.2 Pharmacokinetic properties

Absorption

Ascorbic acid is well absorbed from the gastrointestinal tract.

Distribution

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.

Elimination

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.

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle. In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

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 for both API

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

Plastic Jar and Caps: 2 years

6.4 Special precautions for storage

Plastic Jars and caps: 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 plastic Jars fitted with white plastic caps containing 60 or 30 tablets sealed in a white transparent polyethylene nylon and packed in inner pack containing leaflet.

Pack sizes 60 and 30 Tablets.

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

7. Marketing authorisation holder

Jessy Pharmaceutical company Limited

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Estate Ikeja Lagos