PENDORA-C VITAMIN C SYRUP

1. Name of the medicinal product

PENDORA-C VITAMIN C SYRUP

2. Qualitative and quantitative composition Each 10ml contains 100mg of Ascorbic acid.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form Oral Syrup

Orange colored syrup pleasantly flavored

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 5 years and above:

10ml daily

Accident Victims, male & female adults (especially those bearing children) as well as adults & children above 5 years undergoing surgery or passing

through immune system depressed sickness (e.g. viral infections): should take 20ml (4 teaspoonfuls) 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 20 -40ml in divide doses

Children 6month -3 years: 5ml per day

Children below 6 months: 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.

PENDORA-C syrup should not be given to patients with hyperoxaluria.

4.4 Special warnings and precautions for use

PENDORA C syrup must not be used as a substitute for a balance diet and healthy lifestyle.

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may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8)

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 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.

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.

4.6 Fertility, pregnancy and lactation

Pregnancy

For PENDORA C syrup 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

PENDORA-C VITAMIN C syrup 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, PENDORA-C VITAMIN C syrup has no known effect on an individual's ability to drive or operate machinery.

1.8 Undesirable effects

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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 PENDORA C VITAMIN C syrup 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 maybe 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/A12CB01

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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 5hydroxytryptamine 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 maybe 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.

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.

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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

Microcrystalline cellulose and carmellose sodium

Hydroxpropylcellulose

Citric acid monohydrate

Sodium saccharin

Methyl paraben

Propyl paraben

Sorbitol liquid 70%

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

An amber coloured 200ml pet bottle ROPP cap.

PENDORA-C VITAMIN C SYRUP

Pack sizes 100ml

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

7.Manufacturer : Jehyson Healthcare Limited

8. Marketing authorisation holder

Muchis Healthcare Limited

9. Marketing authorisation number(s)

NA

10. Date of first authorisation/renewal of the authorisation

NA

11. Date of revision of the text

NA