

Legal Category

POM: Over The Counter

- **SmPC**

1. Name of the medicinal product

VITAKRIS-C SYRUP

2. Qualitative and quantitative composition

Each 5 ml contains:

Ascorbic acid
(Vitamin C 100 mg)

Pharmaceutical form

Liquid Syrup

3. Clinical particulars

3.1 Therapeutic indications

VITAKRIS-C SYRUP is used for supplementation of essential amino acids with Vit C, low birth wt in infants, recurrent infections, formulae fed infants & prescorbutic symptoms. VITAKRIS-C SYRUP is used as a supplement in the treatment of conditions associated with deficiency of certain amino acids and vitamins c such as scurvy, slow wound healing, anemia, easy bruising, shortness of breath, fatigue, nosebleed, gastrointestinal problem, frequent infection, dermatitis, chronic gingivitis, impaired formation and maintenance of collagen, impaired multiple hormonal function, increased risk of various cancer, vascular degeneration.

Posology and method of administration

For oral use

The average protective dose of vitamin C for adults is 70 to 150 mg daily. In the presence of scurvy, doses of 300 mg to 1 g daily are recommended.

3.2 Contraindications

Contraindicated in patients known to be hypersensitive to any of its components and in patients with hypervitaminosis.

3.3 Special warnings and precautions for use

None

Precautions

If you take any medication before you start this consults your Doctor or Pharmacist

3.4 Interaction with other medicinal products and other forms of interaction

None

3.5 Fertility, pregnancy and lactation

None

3.6 Effects on ability to drive and use machines

No effect on driving vehicles or operating machines.

3.7 Undesirable effects

Generally multivitamin and multiminerals are well tolerated by the body. Sometimes, reactions could occur, but they disappear rapidly after continuous and regular use. Vitamin C is likely safe for most people when taken by mouth in recommended doses, In some people, vitamin C might cause nausea, vomiting, heartburn, stomach cramps, headache, and other side effects. Other undesirable effects of peritoneal dialysis related to the procedure: catheter site infection, catheter related complication, hypocalcaemia and peritonitis bacterial.

3.8 Overdose Symptoms and signs

Hyper vitaminosis may occur with an intake far in excess of the daily requirement and recommended dosage. The sign and symptoms include dry and pruritic skin desquamations, erythematous dermatitis, distributed hair growth, fissures of lips, pain and tenderness of bone hyperostosis, headache, papiloedema, anorexia, oedema, fatigue, irritability, hemorrhage, fibrosis, sclerosis of central vein cirrhosis. Intra cranial pressure, raised alkaline phosphate and hypocalcaemia have been reported.

4. Pharmacological properties

4.1 Pharmacodynamic properties

Ascorbic Acid:

Vitamin C cannot be synthesised by man therefore a dietary source is necessary. It acts as a cofactor in numerous biological processes including the hydroxylation of proline to hydroxyproline. In

deficiency, the formation of collagen is, therefore, impaired. Ascorbic acid is important in the hydroxylation of dopamine to noradrenaline and in hydroxylations occurring in steroid synthesis in the adrenals. It is a reducing agent in tyrosine metabolism and by acting as an electron donor in the conversion of folic acid to tetrahydrofolic acid is indirectly involved in the synthesis of purine and thymine. Vitamin C is also necessary for the incorporation of iron into ferritin. Vitamin C increases the phagocytic function of leucocytes; it possesses anti-inflammatory activity and it promotes wound healing. Deficiency can produce scurvy. Features include swollen inflamed gums, petechial haemorrhages and subcutaneous bruising. The deficiency of collagen leads to development of thin watery ground substances in which blood vessels are insecurely fixed and readily ruptured. The supportive components of bone and cartilage are also deficient causing bones to fracture easily and teeth to become loose. Anaemia commonly occurs probably due to Vitamin C role in iron metabolism.

4.2 Pharmacokinetic properties

Ascorbic Acid:

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.

Nicotinamide:

Nicotinic acid is absorbed from the gastro-intestinal tract, is widely distributed in the body tissues and has a short half-life.

4.3 Preclinical safety data

None.

5. Pharmaceutical particulars

5.1 List of excipients

Ascorbic Acid, FD&C red#40, FD&C yellow#16, Flavour Orange and Propylene Glycol.

5.2 Incompatibilities

There are no significant incompatibilities with the product.

5.3 Shelf life

3 Years.

5.4 Special precautions for storage

Store in a cool, dark and dry place, below 30°C.

5.5 Nature and contents of container

100 ml amber PET Bottle provided with a measuring cup.

5.6 Special precautions for disposal and other handling

No special requirements for disposal.

6. Marketing authorisation holder

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State,
NIGERIA.

Email: info@krishatpharma.com

7. Marketing authorisation number(s)

NA

8. Date of first authorisation/renewal of the authorisation

NA

9. Date of revision of the text

NA

Company contact details**Address**

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway,Ibadan, Oyo State,
NIGERIA.

Medical Information e-mail

Email: info@krishatpharma.com