

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rubex Orange 1000mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1000mg of Ascorbic Acid.

Excipients: also includes glucose monohydrate 663mg per tablet, sunset yellow FCF (E110) 1.94 mg per tablet, sodium 273 mg per tablet and orange oil [containing natural orange oil and ethanol (0.00131 microlitres per tablet)].

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Effervescent tablet

Mottled orange, flat, circular, orange flavoured effervescent tablets 25mm in diameter.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Rubex is used for the prevention and treatment of ascorbic acid (vitamin C) deficiency.

4.2 Posology and method of administration

To be taken orally.

One tablet to be taken dissolved in water (hot or cold) daily.

Rubex is not recommended for use in children.

4.3 Contraindications

1. Ascorbic acid in doses greater than 1g daily should not be given to patients with hyperoxaluria.
2. Use in diabetic patients. (Due to the presence of glucose)
3. Hypersensitivity to ascorbic acid or to any of the other constituents.

4.4 Special warnings and precautions for use

1. Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid in doses greater than 1g daily as there may be increased urinary oxalate excretion.
2. Ascorbic acid has caused haemolytic anaemia in certain individuals with a deficiency of glucose-6-phosphate dehydrogenase.
3. Increase intake of ascorbic acid over a prolonged period may result in an increase in renal clearance of ascorbic acid, and deficiency may result if withdrawn rapidly.
4. Do not exceed the stated dose.
5. May be harmful to the teeth due to the presence of glucose.
6. Patients with rare glucose-galactose malabsorption should not take this medicine.
7. This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per tablet.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of ascorbic acid and fluphenazine reportedly resulted in decreased fluphenazine plasma concentration.

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.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects include nausea, vomiting, abdominal cramping and headaches. Large doses of ascorbic acid may cause diarrhoea and the formation of renal calcium calculi.

4.9 Overdose

Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and its elimination is usually accompanied by mild diuresis. Large doses may cause diarrhoea and the formation of renal calcium oxalate calculi.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid (vitamin C) is a water soluble vitamin oxidised into dehydroascorbic acid in the body; the two forms take part in oxidation/reduction reactions. Exogenous ascorbic acid is required for collagen formation and tissue repair.

5.2 Pharmacokinetic properties

None.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium
Sodium hydrogen carbonate
Tartaric acid
Glucose monohydrate
Macrogol 4000
Sunset yellow FCF (E110)
Orange oil*
Caprylic/Capric acid triglycerides

*containing natural orange oil and ethanol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 25°C. Store in original container. Keep the tube tightly closed.

6.5 Nature and contents of container

Opaque polypropylene tube with tamper evident polyethylene cap containing a desiccant insert. Each tube contains either 10 or 24 effervescent tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 MARKETING AUTHORISATION HOLDER

Ricesteele Manufacturing Limited
Cookstown Industrial Estate
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Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 95/8/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 May 1987

Date of last renewal: 04 May 2007

10 DATE OF REVISION OF THE TEXT

October 2011