

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rubex Chewable 250mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 250 mg of Ascorbic Acid.

Excipients: Also includes sucrose, 647mg per tablet and Sunset Yellow FCF (E110) 1mg per tablet.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Orange to orange/brown, flat, circular tablet with bevelled edges and scored on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Rubex chewable is used for the prophylaxis and treatment of ascorbic acid deficiency.

4.2 Posology and method of administration

To be taken orally. Chew or suck before swallowing.

Adults:		2 - 4 tablets daily
Children:	9 - 12 years	1 - 2 tablets daily
Children:	4 - 8 years	1 tablet daily

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.
3. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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. Increased 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over a prolonged period may result in an increase in renal clearance of ascorbic acid, and deficiency may result if withdrawn rapidly.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. May be harmful to the teeth due to the presence of sucrose.

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

Sucrose
Mannitol
Maize starch
Saccharin sodium
Povidone
Sunset yellow FCF (E110)
Orange flavour 212284

Sodium Cyclamate
Talc
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package. Keep the jar tightly closed.

6.5 Nature and contents of container

Amber-coloured polyethylene terephthalate (PET) jars sealed with a low density polyethylene (LDPE) jaycap. The jars contains 50 or 150 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

Tablets may be chewed or sucked before swallowing.

7 MARKETING AUTHORISATION HOLDER

Ricesteele Manufacturing Limited
Cookstown Industrial Estate
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 95/8/3

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

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