IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0095/008/001
Case No: 2043890

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ricesteele Manufacturing Ltd

Cookstown Industrial Estate, **Tallaght**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Rubex Lemon 1000 mg Effervescent Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **17/01/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rubex Lemon 1000mg Effervescent Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1000 mg of Ascorbic Acid.

Excipients: Also includes glucose monohydrate 662 mg per tablet, sodium 273 mg per tablet and sucrose.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet
Mottled yellow, flat, round tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

To be taken orally.
One tablet to be taken dissolved in water (hot or cold) up to three times daily.

4.3 Contraindications

1. Ascorbic acid in doses greater than 1 g daily should not be given to patients with hyperoxaluria.
2. Use in diabetic patients (due to the presence of glucose).
3. Patients with rare glucose-galactose malabsorption 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 1 g daily as there may be increased urinary oxalate excretion.
2. Ascorbic acid had 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over a prolonged period may result in an increase in renal clearance of ascorbic acid, and deficiency may result if withdrawn rapidly.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. May be harmful to the teeth due to the presence of glucose.
5. Do not exceed the stated dose.

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 Pregnancy and lactation

Ascorbic acid in doses greater than 1 g 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 stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin Sodium
Tartaric Acid
Sodium Hydrogen Carbonate
Glucose Monohydrate
Quinoline Yellow (E104)
Macrogol 4000
Caprylic/Capric acid triglycerides
Lemon Flavour 213841 (contains sucrose)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Store in the original container. Store below 25°C.

6.5 Nature and contents of container

Opaque polypropylene tube with tamper evident polyethylene cap containing a desiccant insert. Each tube contains 10 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
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 95/8/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 April 1987

Date of last renewal: 08 April 2007

10 DATE OF REVISION OF THE TEXT

August 2007