IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0095/008/005
Case No: 2045922

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 200 mg 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 **18/05/2008**.

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 200 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ascorbic Acid 200 mg.
Each tablet also contains Sucrose 284mg.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.
White, flat, circular tablets about 12.7 mm in diameter, with beveled edges and scored on one face.
The scoreline allows the tablet to be broken for ease of swallowing only. It does not divide the tablet into equal halves.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis and treatment of ascorbic acid deficiency.

4.2 Posology and method of administration

Adults:
Up to 1000mg daily or as directed by the physician.

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 in excess of 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 it is 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 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.

4.8 Undesirable effects

Side effects include nausea, vomiting, abdominal cramping, headaches have been reported. Large doses of ascorbic acid may cause diarrhoea.

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 a mild diuresis. Large doses may cause diarrhoea.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. It is reported to be about 25% bound to body proteins. It is oxidised to dehydroascorbic acid in the body, the two forms taking part in oxidation reduction reactions. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine.

5.2 Pharmacokinetic properties

Ascorbic acid is reversibly oxidised to dehydroascorbic acid; some is metabolised to ascorbate-2-sulphate, which is inactive, and oxalic acid which are excreted in the urine.

5.3 Preclinical safety data

Ascorbic acid is a water soluble vitamin whose pre-clinical profile has been investigated thoroughly and is established.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Maize Starch
Sodium Saccharin
Povidone
Talc
Magnesium stearate
Pregelatinised Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years from date of manufacture.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original container, tightly closed.

6.5 Nature and contents of container

Amber hydrolytic resistance Type III soda-lime-silica glass bottles. The closure is manufactured from Low Density Polyethylene.
Contents: 100 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.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ricesteele Manufacturing Limited
Cookstown Industrial Estate
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 95/8/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th May 1988

Date of last renewal: 18th May 2008

10 DATE OF REVISION OF THE TEXT

June 2008