IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0417/016/004
Case No: 2061607

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

Seven Seas Ltd

Hedon Road, **Marfleet**, **Kingston-Upon-Hull HU9 5NJ**, **England**

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

Haliborange Vitamin C 500mg effervescent tablets (Lemon Flavour)

the particulars of which are set out in 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 **06/08/2009**.

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

Haliborange Vitamin C 500 mg Effervescent Tablets (Lemon Flavour)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ascorbic Acid 500 mg.
Also contains: sucrose 1.030g, glucose 2.0mg, Sodium 264.64mg.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet
Round, unvaulted, speckled, yellowish effervescent tablets with a lemon flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis and treatment of ascorbic acid deficiency.

4.2 Posology and method of administration

Adults and children over 12 years: One tablet to be taken daily. Do not exceed stated dose.

The tablet should be dissolved in water (minimum 150ml) before swallowing.

4.3 Contraindications

Ascorbic acid doses greater than 1g daily should not be given to patients with hyperoxaluria.

4.4 Special warnings and precautions for use

(i) Side effects including nausea, vomiting, abdominal cramping and headaches have been reported. Large doses of ascorbic acid may cause diarrhoea.

(ii) 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.

(iii) Ascorbic acid has caused haemolytic anaemia in certain individuals with deficiency of glucose - 6 - phosphate dehydrogenase deficiency.

(iv) 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.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of ascorbic acid and Fluphenazine reportedly resulted in decreased Fluphenazine plasma

concentrations.

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. Ascorbic acid crosses the placenta and is distributed into breast milk.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None applicable.

4.9 Overdose

Symptoms of overdosage are unlikely following a single acute intake of this product, as Ascorbic acid in excess of the body's needs is rapidly eliminated into urine. Drinking large amounts of water will also help deplete excess Ascorbic acid.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid functions as a co-factor in a number of hydroxylation and amidation reactions by transferring electrons to enzymes that provide reducing equivalents.

5.2 Pharmacokinetic properties

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues.

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

Ascorbic acid in excess of the body's needs is also rapidly eliminated in the urine.

5.3 Preclinical safety data

There are no preclinical data of relevance which are additional to those already included in other sections of the S.P.C.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Citric Acid Anhydrous
Sodium Bicarbonate
Maize Starch
Riboflavin Sodium Phosphate
Sodium Cyclamate
Saccharin Sodium
Lemon Flavours and lemon powder 987325 P0551
consisting of concentrate of lemon maltodextrin tocopherol (E306)

Liquid glucose, spray dried

6.2 Incompatibilities

Not Applicable.

6.3 Shelf Life

Two years.

6.4 Special precautions for storage

Store below 25 ° C.

Keep in original container tightly closed**.**

6.5 Nature and contents of container

Ten (twenty) tablets in a polypropylene tube with polyethylene stopper(filled with desiccating material).

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

Seven Seas Limited
Hedon Road
Marfleet
Kingston-upon-Hull
HU9 5NJ
England

8 MARKETING AUTHORISATION NUMBER

PA 417/16/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 August 2004

Date of last renewal: 06 August 2009

10 DATE OF REVISION OF THE TEXT

August 2010