

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0417/016/001

Case No: 2055218

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 High Strength Vitamin C 1000 mg Effervescent Tablets (Orange)

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 **19/02/2009**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Haliborange High Strength Vitamin C 1000 mg Effervescent Tablets (Orange)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:

Ascorbic acid 1000 mg

Excipients: Each effervescent tablet contains 1080mg sucrose, 1.60mg dried glucose syrup and 225mg sodium.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet

Pale violet white mottled, round, biplanar effervescent tablets with a beveled edge and an odour of blood orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis and treatment of vitamin C deficiency.

4.2 Posology and method of administration

Adults and children over 12 years: One tablet to be taken daily.

DO NOT EXCEED THE STATED DOSE.

The tablet to be dissolve in water (minimum 150 ml) before swallowing.

4.3 Contraindications

Vitamin C doses greater than 1 g daily should not be given to patients with hyperoxaluria.

4.4 Special warnings and precautions for use

Large doses of vitamin C cause diarrhoea.

Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid in doses in excess of 1 g daily as there may be increased urinary oxalate excretion.

Vitamin C has caused haemolytic anaemia in certain individuals with deficiency of glucose-6-phosphate dehydrogenase.

Increased intake of vitamin C over a prolonged period may result in an increase of renal clearance of vitamin C, and deficiency may result if withdrawn rapidly.

Care should be taken in those patients with an increased plasma concentration of iron.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of vitamin C and fluphenazine reportedly resulted in decreased fluphenazine plasma concentrations.

4.6 Pregnancy and lactation

Vitamin C in doses greater than 1 g daily should not be taken during pregnancy since the effect of large doses on the foetus is unknown. Vitamin C crosses the placenta and is distributed into breast milk.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects can include nausea, vomiting, abdominal cramping and headaches.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vitamin C 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

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

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

Vitamin C in excess of the body's needs is also rapidly eliminated in the urine.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium hydrogen carbonate
Citric acid anhydrous
Orange flavour
Beetroot powder

Maize starch
Sodium cyclamate
Saccharin sodium
Riboflavin sodium phosphate
Dried glucose syrup

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Keep tube tightly closed as this product may be sensitive to moisture.
Do not store above 25°C.

6.5 Nature and contents of container

10 or 20 tablets packed in polypropylene container fitted with a 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
Kinston-Upon-Hull HU9 5NJ
England

8 MARKETING AUTHORISATION NUMBER

PA 417/16/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th February 1999

Date of last renewal: 19th February 2009

10 DATE OF REVISION OF THE TEXT

July 2009