IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0416/005/001
Case No: 2020855

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

Seven Seas Health Care Ltd

Hedon Road, **Marfleet**, **Hull**, **Kingston-upon-Hull HU9 5NJ**, **United Kingdom**

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

Vitamin C Plus 200 mg Soft Capsule

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 **26/08/2006**.

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

Vitamin C Plus 200 mg soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 200mg ascorbic acid

Excipients:
Soya-bean oil 213.50mg
Sorbitol solution

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Soft capsule

Purple/maroon, opaque, oval soft geletain capsules containing a pale, brown filling.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis and treatment of ascorbic acid deficiency.

4.2 Posology and method of administration

Adults: one capsule daily
Children (4-12 years): one capsule daily

Do not exceed stated dose.
Oral administration

4.3 Contraindications

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

4.4 Special warnings and precautions for use

1. Side effects including nausea, vomiting, abdominal cramping, headaches have been reported. Large doses of ascorbic acid may cause diarrhoea.
2. 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.
3. Ascorbic Acid has caused haemolytic anaemia in certain individuals with deficiency of glucose-6-phosphate dehydrogenase.
4. Increased intake of ascorbic acid over a prolonged period may result in an increase in renal clearance of ascorbic and deficiency may result if it is withdrawn rapidly.
5. Keep out of reach of children.

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 known.

4.8 Undesirable effects

See section 4.4 Special warnings and precautions for use.

4.9 Overdose

Symptoms of overdosage are unlikely following an acute intake of this product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid is essential for the synthesis of collagen and inter cellular material. Deficiency leads to the development of a well-defined syndrome known as scurvy.
Ascorbic acid is used in the treatment and prevention of ascorbic acid deficiency.

5.2 Pharmacokinetic properties

Ascorbic acid is readily absorbed from the gastro-intestinal tract and absorption of dietary ascorbate is nearly complete. When vitamin C is given in a single dose, absorption decreases from 75% at 1g to 20% at 5g.

Ascorbic acid is present in the plasma and ubiquitously distributed throughout body tissues, which is excessive to the body's needs and is therefore rapidly excreted in the urine as ascorbate-2-sulphate and oxalic acid.

5.3 Preclinical safety data

There are no pre-clinical data of relevance, which are additional to those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citrus Bioflavonoids
Blackcurrant Extract
Refined Soya-Bean Oil
Hydrogenated Vegetable Oil
Yellow Beeswax (E901)
Soya Lecithin (E322)
Gelatin
Glycerol (E422)

Liquid Sorbitol (Non-crystallising) (E420)
Carmine Red (E120)
Black Iron Oxide (E172)
Water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.

6.5 Nature and contents of container

Polypropylene tub with lid enclosing 60 purple/maroon, opaque oval soft gelatin capsules.

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 Health Care Limited
Hedon Road
Marfleet
Kingston-Upon-Hull
HU9 5NJ
UK

8 MARKETING AUTHORISATION NUMBER

PA 416/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th August 1991
Date of last renewal: 26th August 2006

10 DATE OF REVISION OF THE TEXT

December 2006