**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

**(S.I. No.540 of 2007)**

**PA0416/001/001**
Case No: 2058899

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

**Seven Seas Super Vitamin E 200 IU Capsules**

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 **25/05/2009**.

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

Seven Seas Super Vitamin E 200 IU Capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Vitamin E (*dl* alpha Tocopheryl Acetate) 200IU

Excipients: Soya Bean Oil 71.0mg

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, soft. (Capsule)

Orange, clear, oval, soft gelatin capsules containing an oily solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Vitamin supplement.

### 4.2 Posology and method of administration

Adults Only: One capsule daily.

Method of administration
To be taken by oral administration.

### 4.3 Contraindications

1. Known hypersensitivity to vitamin E.
2. Use in children.

### 4.4 Special warnings and precautions for use

1. Diarrhoea and abdominal pain may occur with large doses of vitamin E.
2. Vitamin E has been reported to increase the risk of thrombosis in patients who have any predisposition thereto or who are taking oestrogens. These findings have not been confirmed.

### 4.5 Interaction with other medicinal products and other forms of interaction

None known.

## 4.6 Pregnancy and lactation

Use is contraindicated in pregnancy and in women breast feeding infants.

## 4.7 Effects on ability to drive and use machines

None stated.

## 4.8 Undesirable effects

Diarrhoea and abdominal pain may occur with large doses of vitamin E (i.e. greater than 1 gram daily).

## 4.9 Overdose

Vitamin E is usually well tolerated at the recommended dose. Large doses have occasionally caused gastrointestinal disturbances, fatigue and weakness and, in such instances conservative measures should be adopted.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

As a nutritional (antioxidant) vitamin.

## 5.2 Pharmacokinetic properties

d - l - alpha tocopheryl is absorbed from the gastrointestinal tract, appears in lymph and is widely distributed to tissues. Most of the dose is slowly excreted in bile, the remainder in urine as glucoronides of tocopheronic acid and the α - lactone.

## 5.3 Preclinical safety data

None available.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Soya bean oil
Apo carotenal suspension 20%
Gelatin
Glycerin

## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf Life

3 years

## 6.4 Special precautions for storage

Store below 25°C.

## 6.5 Nature and contents of container

Polypropylene tubs with HDPE screw caps, containing 90 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
Hull
Kingston-upon-Hull HU9 5NJ
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER

PA 416/1/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th May 1989
Date of last renewal: 25th May 2009

## 10 DATE OF REVISION OF THE TEXT

May 2009