**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

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

**PA0417/009/001**
Case No: 2043293

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

**Seven Seas Folic Acid 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 **12/01/2009**.

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 Folic Acid 400 microgram soft capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| Active ingredient | Content per capsule |
|---|---|
| Folic Acid | 400 micrograms |

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Soft capsule (capsule).

Oval capsule with brown opaque shell.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

The specific dose of 400mcg Folic Acid is for the prevention of the first occurrence of Neural Tube Defects, including Spina Bifida, in the developing foetus.

### 4.2 Posology and method of administration

Women planning to become pregnant:

One capsule containing 400mcg Folic Acid to be taken daily before conception and during the first 12 weeks of pregnancy.

Other Adults, Children and Elderly:

The recommended clinical indication and dosage schedule is not relevant to other patient categories.

Method of administration:

Oral administration.

### 4.3 Contraindications

Hypersensitivity to folic acid.
Vitamin $B_{12}$ deficiency.

### 4.4 Special warnings and precautions for use

Caution is advised in patients with folate dependant tumours.

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

Folate status may be affected by a number of drugs, anti-convulsants, oral contraceptives, anti-tuberculous drugs, and Folic Acid antagonists, including aminopterin, methotrexate, pyrimethamine, trimethoprim and sulphonamides. No major incompatibilities have been reported at the recommended dose and indication.

## 4.6 Pregnancy and lactation

The medicinal product is recommended prior to conception and during the first trimester of pregnancy.

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

None Known.

## 4.9 Overdose

No data available. Conservative measures should be adopted.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Folic Acid is a member of the Vitamin B Group. Folic Acid is reduced in the body to tetrahydrofolate, which is a coenzyme for various metabolic processes including the synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is also involved in some amino-acid conversions, and in the formation and utilisation of formate.

## 5.2 Pharmacokinetic properties

Folic Acid is absorbed mainly from the proximal part of the small intestine. The naturally occurring folate polyglutamates are largely deconjugated and reduced prior to absorption. It is the 5 methyltetrahydrofolate, which appears in the portal circulation, where it is extensively bound to plasma proteins.

Folic Acid is rapidly absorbed from normal diets and is distributed in body tissues. The principal storage site is the liver; it is also actively concentrated in the cerebrospinal fluid. There is an enterohepatic circulation for folate; about 4 to 5 µg is excreted in urine daily. Administration of larger doses of Folic Acid leads to proportionately more of the vitamin being excreted in the urine. Folate is distributed into breast milk.

## 5.3 Preclinical safety data

Folic Acid is well documented in the literature and has been available for many years with no major adverse events.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Soya Bean Oil
Hard Vegetable Fat
Beeswax Yellow (E901)
Lecithin (E322)

Gelatin
Glycerol (E422)
Red Iron Oxide Paste (E172)
Black Iron Oxide Paste (E172)
Fractionated Coconut Oil
Purified Water

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

2 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 polypropylene screw caps containing 30, 60, 90 or 120 capsules.

Not all pack sizes may be marketed.

## 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
Kingson-Upon-Hull
HU9 5NJ
England

## 8 MARKETING AUTHORISATION NUMBER

PA 417/9/1

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

Date of first authorisation: 11th July 1997
Date of last renewal: 11th July 2007

## 10 DATE OF REVISION OF THE TEXT

December 2008