

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

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

**PA0417/001/001**

Case No: 2042904

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

**MaxEPA 170 mg/115 mg Soft 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 **12/11/2007**.

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

MaxEPA 170 mg/ 115 mg Soft Capsules

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Eicosapentaenoic Acid (EPA)	170 mg
Docosahexaenoic Acid (DHA)	115 mg

For full list of excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Soft capsule

Clear, colourless, oblong soft gelatin capsules containing 1 gram of clear, golden oil.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For use in patients for whom a reduction in plasma triglyceride levels is judged to be desirable. It should be used in conjunction with appropriate dietary measures.

##### 4.2 Posology and method of administration

Adults: The usual dose is 5 capsules twice daily with food.

Neonates: The use of MaxEPA Capsules has not been established in neonates.

Children: The use of MaxEPA Capsules has not been established in children.

Elderly: As for adult dosage.

##### 4.3 Contraindications

There are no absolute contraindications for this product.

##### 4.4 Special warnings and precautions for use

Patients on MaxEPA Capsules should be maintained on a regular regime with monitoring of lipid biochemistry and coagulation factors.

Do not exceed the recommended daily dose.

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

In view of the potential effect on bleeding time and platelet aggregation, great care should be exercised in patients on concomitant, anti-coagulant therapy or receiving other drugs which may affect coagulation factors, e.g.: aspirin, cephalosporins.

## **4.6 Pregnancy and lactation**

There is no experience of use during pregnancy or in breast feeding. Use should be avoided until further information is available.

## **4.7 Effects on ability to drive and use machines**

On the basis of performance related to driving, the medicine is unlikely to produce an effect.

## **4.8 Undesirable effects**

No major side effects have been reported, although, in some patients, occasional nausea, indigestion, headache, eructation and slight falls in blood pressure have been reported. In a few instances a slight rise in glucose has been reported.

## **4.9 Overdose**

MaxEPA Capsules are composed entirely of constituents which are found as a normal part of the diet, and, as such, may be regarded as harmless at the proposed dosage levels.

Deleterious effects due to overdosage have been shown to be unlikely and studies in rats have shown no upper toxic levels of administration.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

A fish lipid concentrate with a high content of the essential polyunsaturated fatty acids (PUFA) of the W3 series, namely eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The results of the epidemiological studies in Japan and the Eskimos of Greenland, population consuming a high PUFA intake from marine lipid, suggest an association with low incidence of cardiovascular disease, in contrast to the high incidence in populations consuming diets high in saturated fats or those with a high intake of monoenoic acids like rape oil.

## **5.2 Pharmacokinetic properties**

A regular intake of the concentrate in diet leads to a sustained reduction in plasma triglyceride levels and increase in HDL cholesterol levels by four weeks, following which the values remain in a plateau with continued use or return within two to three months to previous levels if the concentrate is discontinued. The PUFA are incorporated into the normal lipid metabolism but are not identified to any extent in depot fat. The mechanism of effect appears to be via inhibition of triglyceride synthesis.

## **5.3 Preclinical safety data**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Tocopheryl acetate

#### Capsule shell

Gelatin

Glycerol (E422)

#### Printing ink

Purified water, propylene glycol, titanium dioxide, hypromellose

### **6.2 Incompatibilities**

No applicable.

### **6.3 Shelf Life**

3 years

### **6.4 Special precautions for storage**

Do not store above 25°C.

Do not refrigerate.

Store in the original package.

### **6.5 Nature and contents of container**

Polypropylene tubs fitted with snap-on polyethylene caps.

Each tub contains 200 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 Limited

Hedon Road

Kingston-upon-Hull

HU9 5NJ

United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA0417/001/001

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

Date of first authorisation: 28 July 1986

Date of last renewal: 28 July 2006

**10 DATE OF REVISION OF THE TEXT**

December 2006