

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

MaxEPA Liquid 780 mg / 530 mg per 5 ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of liquid contains:

Eicosapentaenoic Acid (EPA)	780 mg
Docosahexaenoic Acid (DHA)	530 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution.
A 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: One 5ml spoonful to be taken twice daily with food.

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

Children: The use of MaxEPA Liquid 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 Liquid 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 Liquid 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

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Unopened: 3 years

Once opened: use within one month.

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

150 ml amber glass bottle with a screw cap closure and oil resistant wad.

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

PA 0417/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 28 July 2006

10 DATE OF REVISION OF THE TEXT

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