Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lanepa Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 1000 mg of marine lipid concentrate providing 180 mg of eicosapentaenoic acid and 120 mg of docosahexaenoic acid.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft
Oblong, transparent, soft gelatin capsules containing a transparent, yellow oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of adminstration

Take one or more capsules daily with water at mealtimes.

4.3 Contraindications

None noted.

4.4 Special warnings and precautions for use

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

There is no experience of use in patients with hepatic dysfunction.

4.5 Interaction with other medicinal products and other forms of interaction

In view of a 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

None.

4.8 Undesirable effects

Side effects include nausea, indigestion, headache, occasional slight falls in blood pressure. In a few instances, a slight rise in glucose has been reported.

4.9 Overdose

Overdose is not normally a problem.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A fish lipid concentrate with a high content of the essential polyunsaturated fatty acids (PUFA) of the omega 3 series. Specifically Eicosapentaenoic Acid and Docosahexaenoic Acid. The results of epidemiological studies in Japan and Greenland, populations consuming a high PUFA intake, suggest an association with a low incidence of cardiovascular disease, in contrast to the high incidence in populations consuming diets high in saturated fats.

A regular intake of the concentrate in diet leads to a sustained reduction in plasma triglyceride levels and increase in HDL cholesterol levels by 4 weeks, following which the values remain on a plateau with continued use or return within 2 or 3 months to the previous levels if the concentrate is discontinued. The mechanism of effect appears to be via inhibition of triglyceride synthesis.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

There are no safety concerns with this product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

RRR alpha tocopherol 1000iuE/g
Gelatin
Glycerol

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

30 and 90 capsules in amber glass bottles (USP Type III Glass) fitted with a tamper evident HDPE cap with a self-adhesive wrap around label and contained in a carton.

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

None.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 257/34/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 October 1992.

Date of last renewal: 14 October 2002.

10 DATE OF REVISION OF THE TEXT

October 2002.