

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Dr. Hommels Cod liver oil

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients: *Vitamin A 3500 I.U, Vitamin D 400 I.U, Vitamin E 0.5 IU OMEGA 3 0.9g*

Excipients with known effect: Non

3. PHARMACEUTICAL FORM

Liquid (Light yellowish oil)

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the treatment of combined vitamin deficiencies (DHA, EPA (A, D, E). For children and adults with very poor diet. Supplement in people with cardiovascular diseases,

4.2 Posology and method of administration

Oral route

Dosage: Adult 12 years and above 5ml (1 teaspoonful) Twice daily. Children 4 Years and above: 5ml (teaspoonful) once daily. Infant and Children- Below 4 Years: 2.5ml (1/2 teaspoonful) daily).

4.3 Contraindications

Hypersensitivity to the active ingredients. (Cod Liver Oil)

4.4 Special warnings and precautions for use

Pregnant women and lactating women should consult their doctor before taking

4.5 Interaction with other medicinal products and other forms of interaction

Thiazide diuretics when taken with Vitamin D can raise blood calcium level

4.6 Fertility, pregnancy and lactation

Women who are taking cod liver oil before pregnancy, during pregnancy, and lactation are warned not to take doses greater than those recommended.

4.7 Effect on ability to drive and use machines

Has no influence on the ability to drive and use machines.

4.8 Undesirable effects

In rare cases, rashes may occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to Nafdac Pharmacovigilance,

4.9 Overdose: Vitamins, when taken in excess, can be harmful. However, unlike other drugs, it will take a very large dose of this product to produce undesirable effects. Symptoms of vitamin overdose are not likely to appear with a single dose of: **For toxicity following recent ingestion**, call for immediate medical help. A gastric lavage may be done to prevent tracheal aspiration (inhalation of gastric contents). For delayed manifestations of toxicity, a mineral oil purgative may be taken to reduce absorption of the vitamins and to hasten elimination. Medical consultation must be made to be able to prevent further complications including liver, kidney, heart, and fluid-electrolyte problems.

5.0 PHARMACOLOGICAL PROPERTIES The pharmacological properties of cod liver oil as a type of drug enable it to exert its action. Basically, cod liver oil is a rich source of vitamins A and D, which are important in meeting the normal requirements of people who are deficient in these nutrients. The EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) content are essential in the production of important substances in the body, such as thromboxane A₃ and prostacyclin PG₁₃, as well as being part of nerve tissues.

Vitamins A and D: Vitamin A plays an important role in bone health, dental health and skin health. In addition, supplementation with this vitamin helps prevent vision problems. Furthermore, vitamin D is important in regulating calcium levels, which also promotes bone health.

Dr. HOMMELS: Cod Liver Oil contains omega-3 fatty acids (DHA and EPA), which have been found to reduce the risk of cardiovascular diseases. These substances can reduce inflammation as well, which is associated with many chronic diseases like inflammatory bowel disease, arthritis, diabetes, and heart disease.

5.1 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SMPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients Non Added

Marketing authorisation holder

United African Laboratories Ltd.

9 Tebun Bisiriyu Street, Shasha, Lagos State.

