



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

Summary of Product Characterization (SMPC)

For

Jessy Cod Liver Oil Omega-3 Fish Oil

1. Name of the medicinal product

Jessy Cod Liver Oil Omega-3 Fish Oil

2. Qualitative and quantitative composition

Each 5ml Contains:

Vitamin A4591 – 4646 IU

Vitamin D3.....459 – 465 IU

Vitamin E..... 9.2 IU

Omega-3 Fatty Acids.....1080mg

DHA.....573mg

EPA..... 302mg

3. Pharmaceutical form

Syrup

A Light-Yellow oil liquid filled in 170ml transparent glass bottle

4. Clinical particulars

4.1 Therapeutic indications

- Treatment of High cholesterol, High triglycerides, kidney disease in diabetes patients, High blood pressure, Heart disease, Osteoarthritis Depression, Autoimmune diseases, Glaucoma, Middle ear infections, Skin problems, Burns & Wounds.
- For the prophylaxis or treatment of vitamin deficiencies associated with restricted diets, improper food intake and decreased absorption or utilization.
- It's also indicated in patients with increased requirement for vitamins due to chronic disease or infection.
- It also promotes resistance to cough, cold, chest and bronchial trouble. Vitamins deficiencies, Healthy body, Growth, Vitality and Convalescence.

4.2 Posology and method of administration

Adults

12 years and Above 5ml daily

Children

2.5ml daily

Infants: Consult a doctor or Pharmacist

4.3 Contraindications

Hypersensitivity to the active substance.

4.4 Special warnings and precautions for use

- Cod liver oil may decrease blood pressure if taken with anti-hypertensive medication such as captopril, losartan, hydrochlorothiazide, amlodipine, enalapril, valsartan, and furosemide.
- Cod liver oil interacts with anticoagulant drugs anti-platelet and non-steroidal anti-inflammatory drugs such as aspirin, clopidogrel, diclofenac, ibuprofen, naproxen, enoxaparin, heparin and warfarin. This leads to increases risk in bleeding and bruising when taken together.
- Hypersensitivity reactions may occur to individuals who are allergic to fish products.

4.5 Interaction with other medicinal products and other forms of interaction

Thiazide diuretics with Vitamin D raise calcium levels.

Oestrogen containing contraceptive pills raise plasma levels of Vitamin A.

4.6 Pregnancy and lactation

Do not use during pregnancy and lactation unless advised by your doctor

Doses of vitamins A, D and E in excess of those recommended should be avoided during pregnancy and lactation

4.7 Effects on ability to drive and use machines

None anticipated.

4.8 Undesirable effects

Do not take cod liver oil in conjunction with blood-thinners or if you are taking a medication for high blood pressure. Combining these treatments may cause a severe drop in your blood pressure, which may lead to dizziness, headache, blurred vision or fainting.

4.9 Overdose

A cod liver oil overdose is likely to cause any of the usual cod liver oil side effects, but perhaps more severely. In particular, stomach upset can be expected. In serious cases, an overdose could increase the risk of bleeding, including dangerous internal bleeding (such as gastrointestinal bleeding or bleeding in the brain). Cod liver oil, even at normal dosages, contains large amounts of vitamins D and A. An overdose of cod liver oil is likely to cause problems related to vitamin A and vitamin D toxicity.

It is not known how best to treat a cod liver oil overdose. Therefore, treatment (if necessary) will likely involve supportive care, which consists of treating the symptoms that occur as a result of the overdose. For instance, if an overdose caused bleeding, supportive treatment would include using medications or procedures to stop the bleeding. It is important that you seek prompt medical attention if you believe that you may have taken too much cod liver oil.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Cod liver oil is a rich source of the fat-soluble vitamins A and D. It also contains several unsaturated fatty acids which are essential food factors, while aloe vera reduces free radical generation due to its antioxidant properties.

Pharmacodynamics:

Although the mechanisms of action of omega-3 fatty acids are not entirely understood, it is believed that two major effects cause the reduction of triglycerides (TGs) in the blood. First, omega-3 fatty acids may reduce the synthesis of TGs in the liver due to inhibition of acylCoA: 1, 2-diacylglycerol acyltransferase. Because omega-3 fatty acids such as EPA and DHA have substantial affinity, but are poor substrates for, the enzymes responsible for triglyceride synthesis, the esterification and release of other fatty acids is inhibited. Second, omega-3 fatty acids appear to increase peroxisomal β -oxidation in the liver due

to a high affinity for PPAR subclasses, thereby up-regulating the metabolism of fatty acids in the liver.

5.2 Pharmacokinetic properties

Pre-systemic metabolism is noted to be 50%.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Vitamin E

6.2 Incompatibilities

No major incompatibilities are known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

Keep all medicines out of reach of children.

6.5 Nature and contents of container

The product is presented in 170ml bottle

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

Jessy Pharmaceutical Company Limited

13B Acme Road, Ogba Industrial Estate,

Ikeja Lagos.

8. Manufacturer

Daily sun pharmaceutical Company limited, plot 3 & 4 Tomori industrial Estate, Off Idi-Iroko Road, Ot State Nigeria