

## **EMZOR FRESHSEAS CODLIVER OIL (Cod-Liver Oil 1000mg Capsules)**

### **1. Name of the medicinal product**

Cod-Liver Oil 1000mg Capsules

### **2. Qualitative and quantitative composition**

Each Soft Gelatin Capsule Contains:

Cod Liver Oil BP ..... 1000mg

Excipients.....q.s.

### **3. Pharmaceutical form**

Natural Transparent colored oblong shaped capsules.

### **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 and the Elderly

One to two capsules daily, preferably taken after meals. Do not exceed the stated dose. The capsules should be swallowed whole with water.

##### Children under 12 years of age

Cod Liver Oil Capsules are not recommended for this age group.

### **4.3 Contraindications**

Hypersensitivity to the active substance(s) or to any of the excipients.

### **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 increase the 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 level 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 Effect on ability to drive and use machines**

None anticipated.

### **4.8 Undesirable effects**

Do not take cod liver oil capsules in conjunction with blood-thinners or if you are taking 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 also ever 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 acyl CoA: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  $\beta$ -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**

Presystemic 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**

Cod Liver Oil, Gelatin, Glycerin, Sorbitol, Methyl Paraben, Propyl Paraben & Purified Water.

### **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 content of container**

The product is presented under Aluminium-PVC Blister pack. (2X15 Capsules)

### **6.6 Special precautions for disposal and other handling**

Not applicable.

## **7.0**

### **Applicant/Manufacturer**

#### **Name and Address of Applicant:**

**Name** : **Emzor Pharmaceutical industries limited**  
**Address** : Plot 3C, Block A, Aswani Market Road,  
Isolo, Lagos, Nigeria.

#### **Name and Address of Manufacturer of the Product:**

**Name** : **Emzor Pharmaceutical industries limited**  
**Address** : Plot 3C, Block A, Aswani Market Road,  
Isolo, Lagos, Nigeria