

1.3 Product Information

1.3.1 Summary of product characteristics:

A. SUMMARY OF PRODUCT CHARACTERISTICS :

1- Name of the Medicinal Product:

1.1 Product Name

COD LIVER OIL AND VITAMIN B-COMPLEX CAPSULES

1.2 Dosage Strength

Each soft gelatin capsule contains:

Cod Liver Oil B.P	300 mg.
Vitamin B1 B.P (Thiamine Mononitrate)	1.0 mg.
Vitamin B2 B.P (Riboflavin)	1.0 mg.
Vitamin B6 B.P	1.0 mg.
Nicotinamide B.P	15.0 mg.
Excipients	q.s.

1.3 Dosage Form

capsule

2- Quality and Quantitative Composition:

2.1 Qualitative Declaration

Each soft gelatin capsule contains:

Cod Liver Oil B.P	300 mg.
Vitamin B1 B.P (Thiamine Mononitrate)	1.0 mg.
Vitamin B2 B.P (Riboflavin)	1.0 mg.
Vitamin B6 B.P	1.0 mg.
Nicotinamide B.P	15.0 mg.
Excipients	q.s.

2.2 Quantitative Declaration

Batch Size		100000	Capsules			
MEDICAMENT FORMULATION						
Sr.No.	Ingradiant	Label Claim	Ovr. (%)	mg/ cap	Qty.(Kg)	Qty. (%)
1	Cod liver oil BP	300 mg	NA	300.00	30.000	27.2727
2	Vitamin B1 BP.(Thiamine Mononitrate)	1 mg	20	1.20	0.120	0.1091
3	Vitamin B2 BP. (Riboflavin)	1 mg	20	1.20	0.120	0.1091
4	Vitamin B6 BP.	1 mg	20	1.20	0.120	0.1091
5	Nicotinamide BP.	15 mg	20	18.00	1.800	1.6364
6	Refined soya oil USP	NA	NA	210.40	21.040	19.1273
7	Hydrogenated Vegetable Oil NF	NA	NA	25.00	2.500	2.2727
8	Bees wax BP	NA	NA	12.00	1.200	1.0909
9	Colloidal Silicon Dioxide BP	NA	NA	4.00	0.400	0.3636
10	Lecithin NF	NA	NA	25.00	2.500	2.2727
11	Microcrystalline cellulose BP	NA	NA	2.00	0.200	0.1818
12	Calcium Carbonate BP	NA	NA	500.00	50.000	45.4545
	TOTAL			1100.00	110.0	100.0000

GELATIN MASS FORMULATION : YELLOW OPAQUE COLOR						
Sr.No.	Ingradiant	Rationale	Grade	Qty (%)	Qty (Kg)	mg/cap
1	Gelatin	Film Former	BP	41.600	49.92000	249.60125
2	Glycerin	Plasticizer	BP	6.000	7.20000	36.00018
3	Sorbitol	Plasticizer	BP	12.000	14.40000	72.00036
4	Sodium Methyl Paraben	Preservative	BP	0.160	0.19200	0.96000
5	Sodium Propyl Praben	Preservative	BP	0.040	0.04800	0.24000
6	D & C Yellow No.10	Colorant	IH	0.0600	0.07200	0.36000
8	FD & C Yellow No.6	Colorant	IH	0.0035	0.00420	0.02100
9	Titanium Dioxide	Opacifier	BP	0.2000	0.24000	1.20001
10	Purified Water	Vehicle	BP	39.936	47.92320	239.61720
Total				100.000	120.00	600.000

SPECIFICATIONS						
1	Die Size	23.2 Minim		4	Gross Wt	1700
2	Shell weight	600.000		5	Color	Yellow Opaque
3	Fill weight	1100		6	Shape	Oblong

ABBREVIATIONS					
NA	Not Applicable		BP	British Pharmacopeia	
Ovr.%	Percentage Overages		IH	In House	
mg	Miligram		Kg	Kilogram	
Qty.	Quantity		Cap	Capsule	

3- Pharmaceutical Form:

Yellow coloured, oblong shaped soft gelatin capsules containing yellowish oily liquid

4- Clinical Particulars:

4.1 Therapeutic indications

- a) Treatment of combined vitamins A, D and E deficiencies.
- b) Combined vitamins A, D and E and Polyunsaturates supplement to the diet during childhood and in adults with very poor dietary status.
- c) Traditional remedy in the symptomatic relief of muscular and joint stiffness and aches.

4.2 Posology and method of administration

For mild to moderate deficiency states: 1 capsule per day depending on the age of the patient and the severity of the deficiency. Treatment of the deficiency state should be continued usually between 2 weeks - 2 months, until the deficiency is corrected. As a dietary supplement: Adults and children over 6 years old - 1 capsule per day. Do not exceed the stated dose. To be taken by oral administration.

4.3 Contraindications

Hypersensitivity to any of the ingredients, Hypercalcaemia. Hypervitaminoses A, D or E.

4.4 Special warnings and precautions for use

Do not take other supplements of Vitamin A and D whilst taking this product. Benefits of Cod Liver Oil supplementation in malabsorption syndromes is unlikely.

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 Fertility, 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

4.8 Undesirable effects

Vitamin excess can be harmful but a very large overdose of this product would be needed to produce ill effects.

4.9 Overdose

Symptoms of overdosage are unlikely following a single acute intake of Vitamin A less than 1,500,000 units, Vitamin D less than 50,000 units or Vitamin E less than 500 units. Vitamin A toxicity generally presents as irritability, vomiting, loss of appetite and skin changes. Vitamin D toxicity leads to disturbing of calcium metabolism and calcification of soft tissues including the lungs and kidneys. Vitamin E toxicity may lead to biochemical disturbances such as a fall in thyroid hormone. In case of recent ingestion, gastric lavage is recommended ensuring that tracheal aspiration does not occur. In delayed presentations, administration of mineral oil purgative is recommended to diminish absorption of vitamins as well as to increase gastro intestinal motility. Other symptomatic and supportive measures should be provided when indicated. Hepatic, renal, cardiac and fluid electrolyte status should be carefully monitored.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

The Vitamin A and D content of Cod Liver Oil ensures that normal dietary requirements are met and that Vitamin A and D deficiency states are corrected.

5.2 Pharmacokinetic properties

The essential fatty acids, Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA), found in Cod Liver Oil, undergo beta oxidation, EPA is a precursor of the '3' series of prostaglandins and in a cascade reaction can lead to the production of thromboxane A₂ and prostacyclin PG_I₂. Precise data on the rate of turnover of EPA and DHA in lipids of nervous tissue have not been determined.

5.3 Preclinical safety data

There are no preclinical data of relevance which are additional to those already included in other sections of the SPC.

6- Pharmaceutical Particulars:**6.1 List of excipients**

Gelatin
Glycerin
Sorbitol
Sodium Methyl Paraben
Sodium Propyl Paraben
D & C Yellow No.10
FD & C Yellow No.6
Titanium Dioxide
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store at a room temperature away from heat and moisture

6.5 Nature and contents of container

15 capsule packed in one blister. Such 2 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.



OLIVE HEALTHCARE LTD

7- Marketing Authorization Holder:

NAME: OLIVE HEALTHCARE LTD
ADDRESS: 197/2, Athiyawad,, Dabhel Village,
Nani Daman, Daman and Diu,
India 396210
COUNTRY: INDIA

8- Marketing Authorization Number (s):

-Product license / registration Number (s)

9- Manufacturer Name:

NAME: OLIVE HEALTHCARE LTD
ADDRESS: 197/2, Athiyawad,, Dabhel Village,
Nani Daman, Daman and Diu,
India 396210
COUNTRY: INDIA

10- Date of first authorization/renewal of the authorization:

11- Date of revision of the text:
