

PREFERA OB PLUS DHA- folic acid, heme iron polypeptide, iron dextran, potassium iodide, zinc oxide, selenium, cupric sulfate, cholecalciferol, thiamine mononitrate, alpha-tocopherol succinate, d-, riboflavin, niacinamide, pyridoxine hydrochloride, cyanocobalamin, biotin, and calcium pantothenate tablet
Alaven Pharmaceutical LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Prefera OB®
+ DHA
The Prenatal YOU CAN COUNT ON!

Prenatal/Postnatal Multivitamin/Multimineral
PreferaOB® Tablets & life'sDHA™¹ Softgels

Rx Only

¹ *life'sDHA™* is a trademark of Martek Biosciences Corporation, Columbia, MD.

DESCRIPTION

PreferaOB® + DHA is a prescription prenatal/postnatal multivitamin/multimineral (*PreferaOB®*) and Omega-3 fatty acid (*life'sDHA™*) nutritional supplement. PreferaOB® + DHA is a small, oval, film-coated, purple tablet with black core, debossed and bisected with "AP/88" on one side, and plain on the other (*PreferaOB®*) and a clear essential fatty acid softgel containing an amber to light/dark orange semi-solid mixture (*life'sDHA™*).

Each PreferaOB® tablet contains:

VITAMINS		MINERALS	
D3 (as cholecalciferol)	400 IU	Iron	
E (as d-alpha tocopheryl succinate)	10 IU	as PIC (polysaccharide iron complex)	22 mg
B1 (as thiamin mononitrate)	1.5 mg	as HIP (heme iron polypeptide as Proferrin®* –	
B2 (as riboflavin)	1.6 mg	bovine source, USDA certified)	6 mg
B3 (niacin as niacinamide)	17 mg	Iodine (as potassium iodide)	175 mcg
B6 (as pyridoxine HCl)	50 mg	Zinc (as zinc oxide)	15 mg
Folic Acid	1 mg	Selenium (as sodium selenate)	65 mcg
B12 (as cyanocobalamin)	12 mcg	Copper (as cupric sulfate)	0.8 mg
Biotin	30 mcg		
B5 (as d-calcium pantothenate)	10 mg		

* Proferrin® is a registered trademark of Colorado Biolabs, Inc., Cozad, NE.

INACTIVE INGREDIENTS

Microcrystalline cellulose, croscarmellose sodium, crospovidone, magnesium stearate, silicon dioxide, dextran, dicalcium phosphate, sucrose, protease, modified food starch, dl-alpha tocopherol, sodium ascorbate, ethylcellulose, resin, coating (polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, D&C red no. 30 aluminum lake, FD&C blue no. 2 aluminum lake).

Each *life'sDHA*[™] Softgel contains: Docosahexaenoic Acid (DHA) 200 mg
DHA is derived from the oils of microalgae. Inactive ingredients in the DHA softgel include: gelatin, glycerin USP, water.

INDICATIONS AND USAGE

PreferaOB[®] + DHA is a prescription multivitamin/multimineral (*PreferaOB*[®]) and Omega-3 fatty acid (*life'sDHA*[™]) nutritional supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. PreferaOB[®] + DHA is also beneficial in improving the nutritional status of women prior to conception.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNING

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ratio (INR). Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding diathesis.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **Keep this product out of reach of children.** In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS

Folic acid when administered as a single agent in doses above 0.1mg daily may obscure pernicious anemia in that hematological remission can occur while neurological manifestations remain progressive. Pregnant women and nursing mothers should avoid supplemental doses of vitamin E higher than RDA amounts. While prescribing this nutritional supplement for pregnant women, nursing mothers, or for women prior to conception, their medical condition and other drugs, herbs, and/or supplements consumption should be considered.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION

One tablet and one softgel daily with or without food, or as prescribed by a licensed health care provider with prescribing authority.

HOW SUPPLIED

PreferaOB[®] + DHA is supplied in child-resistant blister packs of 30 tablets and 30 softgels (NDC 68220-089-30) and as a Professional Sample (NDC 68220-089-25).

KEEP OUT OF REACH OF CHILDREN.

STORAGE

Store at controlled room temperature 20°-25°C (68°-77°F). Excursions permitted to 15°-30°C (59°-86°F). [See current USP]

Dispense in a tight, light-resistant container to protect from light and moisture.

For medical inquiries call toll free 1-888-317-0001

www.PreferaOB.com

Manufactured for:

Alaven® Pharmaceutical LLC, Marietta, GA 30062

Patents Pending

PreferaOB® is a registered trademark of Alaven® Pharmaceutical LLC, Marietta, GA.

089-0709-01

Ref CL-089-0709-01

PRINCIPAL DISPLAY PANEL - 30 Tablets + 30 Softgels Carton

Rx Only

NDC 68220-089-30

30 Tablets + 30 Softgels

PreferaOB®

+ DHA

The Prenatal YOU CAN COUNT ON!

ONLY prenatal with Natural, Body-Ready HEME Iron + DHA

15 Essential Vitamins and Minerals including:

- **Plant-based *life'sDHA*™ Omega-3**
- **High dose of vitamin B₆**
- **1mg of folic acid**

ACTUAL
SIZE

Pre/Post-natal Nutritional
Supplement + DHA

www.PreferaOB.com



PREFERA OB PLUS DHA

folic acid, heme iron polypeptide, iron dextran, potassium iodide, zinc oxide, selenium, cupric sulfate, cholecalciferol, thiamine mononitrate, alpha-tocopherol succinate, d-, riboflavin, niacinamide, pyridoxine hydrochloride, cyanocobalamin, biotin, and calcium pantothenate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68220-089
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
Heme Iron Polypeptide (UNII: 31VDO12CJY) (Heme Iron Polypeptide - UNII:31VDO12CJY)	Heme Iron Polypeptide	6 mg
IRON DEXTRAN (UNII: 95HR524N2M) (IRON DEXTRAN - UNII:95HR524N2M)	IRON DEXTRAN	22 mg
Potassium Iodide (UNII: 1C4QK22F9J) (Iodine - UNII:9679TC07X4)	Potassium Iodide	175 ug
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc - UNII:J41CSQ7QDS)	Zinc Oxide	15 mg
Selenium (UNII: H6241UJ22B) (Selenium - UNII:H6241UJ22B)	Selenium	65 ug
CUPRIC SULFATE (UNII: LRX7AJ16DT) (COPPER - UNII:789U1901C5)	CUPRIC SULFATE	0.8 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)	THIAMINE MONONITRATE	1.5 mg
ALPHA-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (ALPHA-TOCOPHEROL SUCCINATE, D- - UNII:LU4B53JYVE)	ALPHA-TOCOPHEROL SUCCINATE, D-	10 [iU]
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.6 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	17 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	50 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	30 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (CALCIUM PANTOTHENATE - UNII:568ET80C3D)	CALCIUM PANTOTHENATE	10 mg

Inactive Ingredients		
Ingredient Name		Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		66 mg
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		51.5 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)		5 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		5 mg
DEXTRAN 1 (UNII: I8LHQ0D645)		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)		
SUCROSE (UNII: C151H8M554)		
ASPERGILLUS FLAVUS VAR. ORYZAE PROTEASE (UNII: Z3GVO2327F)		
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)		
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)		
SODIUM ASCORBATE (UNII: S033EH8359)		
ETHYLCELLULOSE (UNII: 7Z8S9VYZ4B)		
POLYVINYL ALCOHOL (UNII: 532B59J990)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
D&C RED NO. 30 (UNII: 2S42T2808B)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		

Product Characteristics			
Color	PURPLE	Score	2 pieces
Shape	OVAL	Size	15mm

Flavor		Imprint Code	AP;88	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68220-089-05	5 in 1 BLISTER PACK		
2	NDC:68220-089-30	30 in 1 CARTON		
3	NDC:68220-089-05	5 in 1 BLISTER PACK		
4	NDC:68220-089-25	5 in 1 CARTON		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
UNAPPROVED DRUG OTHER		04/01/2009		

Labeler - Alaven Pharmaceutical LLC (140210829)

Establishment			
Name	Address	ID/FEI	Business Operations
Nexgen Pharma Inc.		160356114	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Carton Services Inc		004215968	REPACK

Revised: 2/2010

Alaven Pharmaceutical LLC