

PREFERAOB ONE- folic acid, heme iron polypeptide, iron dextran, potassium iodide, zinc oxide, ascorbic acid, cholecalciferol, doconexent, .alpha.-tocopherol acetate, dl-, niacinamide, pyridoxine hydrochloride, cyanocobalamin, biotin and calcium pantothenate capsule capsule 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.

PreferaOB ONE™

**Prenatal/Postnatal Multivitamin/
Multimineral/DHA softgel**

Rx Only

DESCRIPTION

PreferaOB ONE™ is a prescription prenatal/postnatal multivitamin/multimineral nutritional supplement with Omega-3 fatty acid (*life'sDHA™1*). PreferaOB ONE™ is an oblong shaped, opaque purple colored softgel, imprinted "AP 86" in white ink on one side and plain on the other.

Each PreferaOB ONE™ Softgel contains:

Vitamin C (as ascorbic acid)	25 mg
Vitamin D3 (as cholecalciferol)	400 IU
Vitamin E (as dl-alpha tocopheryl acetate)	10 IU
Vitamin B3 (niacin as niacinamide)	17 mg
Vitamin B6 (as pyridoxine HCl)	50 mg
Folic Acid	1 mg
Vitamin B12 (as cyanocobalamin)	12 mcg
Biotin	30 mcg
Vitamin B5 (as d-calcium pantothenate)	10 mg
Iron	
as PIC (polysaccharide iron complex)	22 mg
as HIP (heme iron polypeptide as Proferrin®* -bovine source, USDA certified)	6 mg
Iodine (as potassium iodide)	175 mcg
Zinc (as zinc oxide)	15 mg
<hr/> Docosahexaenoic Acid (DHA)	<hr/> 200 mg

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

DHA is derived from the oils of microalgae, which is grown outside of the ocean, in a controlled environment, eliminating the risk of oceanic contamination.

Inactive Ingredients

Gelatin, soybean oil, yellow beeswax, and lecithin.

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

INDICATIONS AND USAGE

PreferaOB ONE[™] is a prescription multivitamin/multimineral nutritional supplement with Omega-3 fatty acid (*life'sDHA*[™]) indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and non-lactating mothers. PreferaOB ONE[™] 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 0.1 mg 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 softgel daily with or without food, or as prescribed by a licensed health care provider with prescribing authority.

HOW SUPPLIED

PreferaOB ONE[™] is supplied in child-resistant blister packs of 30 softgels (NDC 68220-086-30) and as a Professional Sample (NDC 68220-086-25).

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]

To protect from light, dispense in carton provided. Once open, blisters should be stored in carton.

For medical inquiries call toll free

1-888-317-0001

www.PreferaOB.com

Manufactured for:

Alaven® Pharmaceutical LLC

Marietta, GA 30062

U.S. Patent No. 7,585,527

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

CL6-086-00-01-1209a

PRINCIPAL DISPLAY PANEL - 30 Softgels Blister Package

Rx Only

NDC 68220-086-30

30 Softgels

PreferaOB ONE™

The Prenatal YOU CAN COUNT ON!

**FIRST and ONLY prenatal with Natural,
Body-Ready HEME Iron + DHA In
an all-in-one softgel**

12 Essential Vitamins
and Minerals including:

- High dose of vitamin B₆
- 1mg of folic acid

Plus Plant-based life'sDHA™ Omega-3

Pre/Post-natal Nutritional

Supplement + DHA

life'sDHA™

www.PreferaOB.com

Rx Only NDC 68220-086-30
30 Softgels



The Prenatal YOU CAN COUNT ON!

FIRST and ONLY prenatal with Natural, Body-Ready HEME Iron + DHA in an all-in-one softgel!

12 Essential Vitamins and Minerals including:
- High dose of vitamin B₆
- 1mg of folic acid

Plus Plant-based life'sDHA™ Omega-3

Pre/Post-natal Nutritional Supplement + DHA

www.PreferaOB.com

Rx Only NDC 68220-086-30
30 Softgels



The Prenatal YOU CAN COUNT ON!

FIRST and ONLY prenatal with Natural, Body-Ready HEME Iron + DHA in an all-in-one softgel!

12 Essential Vitamins and Minerals including:
- High dose of vitamin B₆
- 1mg of folic acid

Plus Plant-based life'sDHA™ Omega-3

Pre/Post-natal Nutritional Supplement + DHA

www.PreferaOB.com



INDICATIONS AND USAGE
PreferaOB ONE™ is a prescription multivitamin/mineral/nutritional supplement with Omega-3 fatty acid (fish oil) indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both feeding and non-feeding mothers. PreferaOB ONE™ 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 adverse reproductive 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 diatheses.

WARNING
Accidental overdosage 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 0.1 mg daily may obscure neurologic symptoms that neurologically inborn errors of folate which neurologically 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 pre or 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.

DOSE AND ADMINISTRATION
One softgel daily with or without food, or as prescribed by a licensed health care provider with prescribing authority.

HOW SUPPLIED
PreferaOB ONE™ is supplied in child-resistant blister packs of 30 softgels (NDC 68220-086-30) and as a Professional Sample (NDC 68220-086-25).

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).

To protect from light, dispense in carton provided. Once open, blisters should be stored in carton.

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

www.PreferaOB.com

Manufactured for:
Avera® Pharmaceutical LLC, Marietta, GA 30067
US Patent # 7,283,227
*PreferaOB™ is a trademark of Avera® (Avera® Corporation, Columbia, MO)
*DHA™ is a registered trademark of C. DuBois Roberts, Inc., Great Hill
PreferaOB ONE is a registered trademark of PreferaOB ONE™, a trademark of Avera® Pharmaceutical LLC, Marietta, GA

life'sDHA™
plant-based omega-3 fatty acid

4-886-30-04-2218

PREFERAOB ONE

folic acid, heme iron polypeptide, iron dextran, potassium iodide, zinc oxide, ascorbic acid, cholecalciferol, doconexent, .alpha.-tocopherol acetate, dl-, niacinamide, pyridoxine hydrochloride, cyanocobalamin, biotin and calcium pantothenate capsule capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68220-086
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) (Potassium Cation - UNII:295O53K152)	Potassium Iodide	175 ug
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	15 ug
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	25 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	200 mg
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL ACETATE, DL- - UNII:WR1WPI7EW8)	.ALPHA.-TOCOPHEROL ACETATE, DL-	10 [iU]
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
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	58 mg
WAX, YELLOW (UNII: 2ZA36H0S2V)	34 mg
GELATIN (UNII: 2G86QN327L)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	10 mg

Product Characteristics

Color	PURPLE	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	AP;86
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68220-086-30	6 in 1 CARTON		
1	NDC:68220-086-05	5 in 1 BLISTER PACK		
2	NDC:68220-086-25	1 in 1 CARTON		
2	NDC:68220-086-05	5 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		04/01/2010	

Labeler - Alaven Pharmaceutical LLC (140210829)

Establishment

Name	Address	ID/FEI	Business Operations
International Vitamin Corporation		961594343	MANUFACTURE

Establishment

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

Revised: 3/2010

Alaven Pharmaceutical LLC