

**SELECT-OB PLUS DHA PRENATAL SUPPLEMENT PLUS DHA- .beta.-carotene, vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, levomefolate calcium, cobalamin, iron, magnesium oxide, zinc oxide, and doconexant
Exeltis USA, Inc.**

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.

Select-OB+DHA ®

0642-0075-30

Prenatal Supplement with DHA

Rx

COMPOSITION

Each SELECT-OB ® caplet contains:

Vitamin A (as retinyl acetate & beta carotene)	510 mcg RAE (1700 IU)
Vitamin C (as ascorbic acid)	60 mg
Vitamin D (as cholecalciferol)	10 mcg (400 IU)
Vitamin E (as dl-alpha tocopheryl acetate)	13.5 mg (30 IU)
Thiamin (Vitamin B1 as thiamine mononitrate)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	15 mg NE
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate (as folic acid)	1700 mcg DFE
Vitamin B12 (as cyanocobalamin)	5 mcg
Iron (as polysaccharide iron complex)	29 mg
Magnesium (as magnesium oxide)	25 mg
Zinc (as zinc oxide)	15 mg

Each softgel capsule contains:

Docosahexaenoic acid (DHA) (from natural algal oil)	250 mg
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Other Ingredients in Select-OB ® caplet: Fructose, Stearic Acid, Mono and Diglycerides, Croscarmellose Sodium, Mixed Berry Flavor WONF, Gelatin (Porcine), Silicon Dioxide, Citric Acid, Magnesium Stearate, Modified Food Starch, Hydroxypropylmethyl Cellulose, Malic Acid, Sucrose, Corn Starch, Dicalcium Phosphate, Sodium Ascorbate, Medium Chain Triglycerides, Sorbic Acid, Tocopherol Concentrate, Sodium Benzoate, dl-Alpha-Tocopherol, Butylated Hydroxytoluene (BHT), Tricalcium Phosphate. Coating: Hydroxypropylmethyl Cellulose, Titanium Dioxide, Polydextrose,

Hydroxypropyl Cellulose, Triacetin, Polyethylene Glycol, FD&C Blue #1 / Aluminum Lake, FD&C Blue #2 / Aluminum Lake. **Contains: Soy**

Other Ingredients in DHA softgel capsule: Gelatin, Glycerin USP, Water.

INDICATIONS AND USAGE

Select-OB+DHA[®] is indicated to provide vitamin, mineral, and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.*

Select-OB+DHA[®] does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS

Select-OB+DHA[®] is contraindicated in patients with hypersensitivity to any of its components or color additives. Folic acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid. Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (vitamin B12).

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 a Poison Control Center immediately.

WARNINGS/PRECAUTIONS

Select-OB+DHA[®] should be used with caution in patients with known sensitivity or allergy to soy.

Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur. Prolonged use of iron salts may produce iron storage disease.

Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive. The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency. Consumption of more than 3 grams of omega-3 fatty acids per day from all sources may lead to excessive bleeding.

Supplemental intake of omega-3 fatty acids such as DHA exceeding 2 grams per day is

not recommended.

Avoid overdose. Keep out of the reach of children.

Drug Interactions

High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs.

Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones.

Zinc can inhibit the absorption of certain antibiotics; take at least 2 hours apart to minimize interactions. Consult appropriate references for additional specific vitamin-drug interactions.

Information for Patients

Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breast-feeding.

Pediatric Use

Not for pediatric use.

ADVERSE REACTIONS

Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in Select-OB+DHA[®].

DOSAGE AND ADMINISTRATION

Before, during and after pregnancy, chew or swallow one blue Select OB[®] caplet and swallow one DHA softgel capsule daily, or as directed by a physician.

HOW SUPPLIED

Select-OB+DHA[®] is available as a light blue caplet debossed EV0077 and one amber-colored DHA softgel capsule. Available in Box of Unit-Dose pack of 30 (5 child resistant blister cards of 6 SELECT-OB[®] caplets and 6 DHA softgel capsules each) (0642-0075-30) and as professional samples (0642-0075-03).

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat and moisture.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Rx

Distributed by:

Exeltis USA, Inc.

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1-877-324-9349

www.exeltisusa.com

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U.S. Patent No. 7,560,123; 8,101,587; 8,197,855; and 8,609,629

Select-OB+DHA[®] is a trademark of Exeltis Healthcare, S.L.

Rev. January 2023 0753001-02

PRINCIPAL DISPLAY PANEL - Kit Carton

0642-0075-30

Select-OB+DHA[®]

Prenatal Supplement with DHA

Berry flavored BLUE Select-OB[®] Caplet
can be chewed or swallowed

DHA Softgel Capsule

from natural source DHA

Smaller DHA Softgel

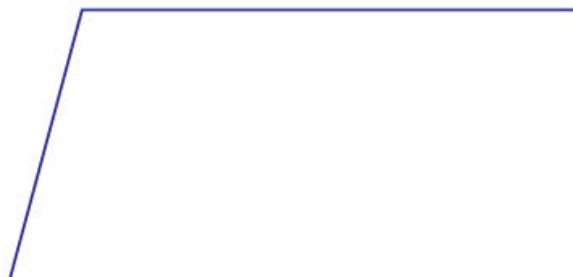
DOES NOT CONTAIN
FISH OIL

R x

Unit Dose Pack

30 Caplets and 30 Softgel Capsules

U.S. Patented



0642-0075-30

Select-OB⁺DHA

Prenatal Supplement with DHA

Berry flavored BLUE Select-OB⁺ Caplet can be chewed or swallowed

DHA Softgel Capsule from natural source DHA



New
Smaller DHA Softgel



R_x

Unit Dose Pack
30 Caplets and 30 Softgel Capsules

U.S. Patented



Select-OB⁺DHA

Prenatal Supplement with DHA

Supplement Facts

Serving Size 1 Caplet and 1 Softgel Capsule

Each Caplet contains		% Daily Value in Pregnancy
Vitamin A (as acetate and beta carotene)	1700 IU	21%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D3 (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamine Mononitrate (Vitamin B1)	1.6 mg	94%
Riboflavin (Vitamin B2)	1.8 mg	90%
Niacin (as niacinamide)	15 mg	75%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folic acid	1 mg	125%
Vitamin B12 (as cyanocobalamin)	5 mcg	63%
Elemental Iron (as polysaccharide iron complex)	29 mg	161%
Magnesium (as magnesium oxide)	25 mg	6%
Zinc (as zinc oxide)	15 mg	100%
Each Softgel Capsule contains		
Algal OMEGATEX0063TGCH (derived from natural algal oil) (* providing 250mg DHA (docosahexaenoic acid))	486 mg*	†

† Daily Value not established

Other Ingredients in Select-OB⁺ Caplet: Fructose, Stearic Acid, Mono and Diglycerides, Croscarmellose Sodium, Mixed Berry Flavor WONE, Gelatin (Porcine), Silicon Dioxide, Citric Acid, Magnesium Stearate, Modified Food Starch, Hydroxypropylmethyl Cellulose, Malic Acid, Sucrose, Corn Starch, Dicalcium Phosphate, Sodium Ascorbate, Medium Chain Triglycerides, Sorbic Acid, Tocopherol Concentrate, Sodium Benzoate, dl-Alpha-Tocopherol, Butylated Hydroxytoluene (BHT), Tricalcium Phosphate. Coating: Hydroxypropylmethyl Cellulose, Titanium Dioxide, Polydextrose, Hydroxypropyl Cellulose, Triacetin, Polyethylene Glycol, FD&C Blue #1 / Aluminum Lake, FD&C Blue #2 / Aluminum Lake. Contains: Soy. Other Ingredients in DHA Softgel Capsule: Gelatin, Glycerin USP, Water.

Unit Dose Pack
30 Caplets and 30 Softgel Capsules
U.S. Patented Rx



Select-OB[®]+DHA

Prenatal Supplement with DHA

0642-0075-30

INDICATIONS AND USAGE: Select-OB[®]+DHA is indicated to provide vitamin, mineral, and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother, including individuals with known allergies to fish. Select-OB[®]+DHA does not contain fish, fish oils, fish proteins or fish byproducts.

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 a Poison Control Center immediately.

DOSAGE AND ADMINISTRATION: Before, during and after pregnancy, chew or swallow one blue Select-OB[®] caplet and swallow one DHA softgel capsule daily, or as directed by a physician.

HOW SUPPLIED: Select-OB[®]+DHA is available as a light blue caplet debossed EV0077 and one amber-colored DHA softgel capsule. Available in Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5 Select-OB[®] caplets and 5 DHA softgel capsules each), (NDC 0642-0075-30) and as professional samples (NDC 0642-0075-03).

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat and moisture.

Rx
See package insert for full prescribing information

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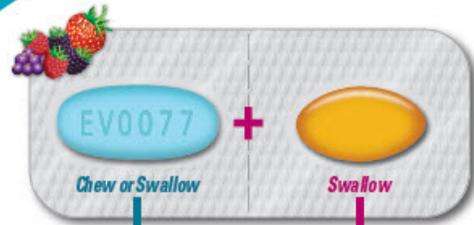
Select-OB[®]+DHA

Prenatal Supplement with DHA

Berry flavored BLUE Select-OB[®] Caplet
can be chewed or swallowed
DHA Softgel Capsule
from natural source DHA



•Lactose, Gluten and
Fish By-Product Free



Select-OB[®] + DHA
(DAILY DOSE)

Lot No.

NO VARNISH AREA FOR
LOT NO & EXP DATE IMPRINT

Exp. Date:

SELECT-OB PLUS DHA PRENATAL SUPPLEMENT PLUS DHA

.beta.-carotene, vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, levomefolate calcium, cobalamin, iron, magnesium oxide, zinc oxide, and doconexant kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0642-0075
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0075-30	1 in 1 CARTON	04/08/2009	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOX	30
Part 2	1 BOX	30

Part 1 of 2

SELECT-OB

.beta.-carotene, vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, levomefolate calcium, cobalamin, iron, magnesium oxide, and zinc oxide tablet, coated

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	600 [iU]
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1100 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.6 mg

RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.8 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	15 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.4 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	0.6 mg
COBALAMIN (UNII: 8406EY2OQA) (COBALAMIN - UNII:8406EY2OQA)	COBALAMIN	5 ug
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	29 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	25 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
FRUCTOSE (UNII: 6YSS42VSEV)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL (UNII: 248HN3Z28U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
TRIACETIN (UNII: XHX3C3X673)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
SODIUM ASCORBATE (UNII: S033EH8359)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SORBIC ACID (UNII: X045WJ989B)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	19mm
Flavor	BERRY (Mixed Berry)	Imprint Code	EV0077

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOX; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/08/2009	

Part 2 of 2**DHA**

doconexant capsule

Product Information**Route of Administration** ORAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	250 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow (Amber)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	
Contains			

Packaging

Item	Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOX; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		04/08/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/08/2009	

Labeler - Exeltis USA, Inc. (071170534)

Registrant - Exeltis USA, Inc. (071170534)

Revised: 7/2023

Exeltis USA, Inc.