OBTREX DHA COMBO PACK- docosahexaenoic acid, beta carotene, ascorbic acid, cholecalciferol, dl-alpha tocopheryl acetate, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, l-5-methyltetrahydrofolate calcium, cyanocobalamin, carbonyl iron, magnesium oxide, zinc oxide, sodium selenate

**Pronova Corporation** 

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**OBTREX DHA Combo Pack** 

## **OBTREX DHA Softgels**

Supplement Facts		
Serving Size: 1 Softgel /		
Servings Per Container: 30		
	Amount	% Daily
	Per Serving	Value
DHA (docosahexaenoic acid)	350 mg	*
* % Daily Value not established.		

#### OTHER INGREDIENTS:

Gelatin, Glycerine, Purified Water, Sodium Alginate, Stearic Acid. This product contains purified fish oil.

**OBTREX™ DHA** Omega-3 Fatty Acids are manufactured under cGMP, CFIA and HACCP standards and are also in compliance with the Global Organization of DHA Omega-3 standards.

#### INDICATIONS:

**OBTREX™ DHA** combination pack is indicated to provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period for both lactating and non-lactating mothers. **OBTREX™ DHA** combination pack is also useful in improving nutritional status prior to conception.<sup>†</sup>

†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.

#### **DOSAGE AND ADMINISTRATION:**

One softgel daily; before, during and after pregnancy, with or without food, or as directed by a physician.

#### **PRECAUTIONS:**

Ingestion of more than 3 grams per day of omega-3 fatty acids, such as DHA (docosahexaenoic acid) has been shown to have potential anti-thrombotic effects, including increased bleeding times. Administration of **OBTREX™ DHA** Omega-3 Fatty Acids should be avoided in patients taking anticoagulants.

Sold in combination with **OBTREX™ DHA** Prenatals

#### STORAGE:

Store at room temperature, USP

# Keep out of the reach of Children

To report a serious adverse event or to obtain product information, contact (866) 703-3508.

Rev 10/20

**Dietary Supplement** 

ENTERIC COATED TO HELP PREVENT BURP BACK

### DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

## **OBTREX DHA Caplets**

Supplement Facts		
Serving Size: 1 Caplet /		
Servings Per Container: 30		
	Amount	% Daily
	Per Serving	Value**
Vitamin A (as Beta Carotene)	810 mcg	62%
Vitamin C (as Ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg	67%
Vitamin E (as dl-Alpha	8.1 mg	43%
Tocopheryl Acetate)	0.1 1119	4370
Thiamin (as Thiamine HCI)	3 mg	214%
Riboflavin	3.4 mg	213%
Niacin (as Niacinamide)	20 mg	111%
Vitamin B6 (as Pyridoxine HCl)	40 mg	2000%
Folate (as L-5-	1700 mcg	
Methyltetrahydrofolate	DFE	283%
Calcium)		
	(1000 mcg	
	Folic Acid)	
Vitamin B12 (as	12 mcg	429%
Cyanocobalamin)		
Iron (as Carbonyl Iron)	29 mg	107%

Magnesium (as Magnesium Oxide)	30 mg	8%
Zinc (as Zinc Oxide)	25 mg	192%
Selenium (as Sodium Selenate)	65mcg	93%
* Daily Value (DV) for Pregnant and		
Lactating Women.		

#### **OTHER INGREDIENTS:**

Microcrystalline Cellulose, Methacrylic Acid Copolymer, Croscarmellose Sodium, Gelatin, Stearic Acid, Hypromellose, Maltodextrin, Crospovidone, Starch, Silica, Titanium Dioxide, Triacetin, Sucrose, Citric Acid, Magnesium Stearate, Sodium Lauryl Sulfate, Polyvinylpyrrolidone, Soy Polysaccharide, Mineral Oil, Riboflavin, FD&C Yellow #6 Lake, Sodium Ascorbate, Polyethylene Glycol, Trisodium Citrate, Tocopherols, Tricalcium Phosphate, Glycerol Monostearate, Triethyl Citrate, Ascorbyl Palmitate, Triglycerides, Sodium Benzoate, Polysorbate 80, Sorbic Acid and Talc. **Contains soy**.

#### **DESCRIPTION:**

**OBTREX™ DHA** combination pack is indicated to provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period for both lactating and non-lactating mothers.

**OBTREX™ DHA** combination pack is also useful in improving nutritional status prior to conception.†

†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.

#### **DOSAGE AND ADMINISTRATION:**

One caplet daily or as directed by a physician.

#### **CONTRAINDICATIONS:**

**OBTREX™ DHA** is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

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

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B-12 is deficient

#### **PRECAUTIONS:**

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

#### **ADVERSE REACTIONS:**

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

#### STORAGE:

Store at room temperature, USP.

## Keep out of the reach of Children

To report a serious adverse event or to obtain product information, contact (866) 703-3508.

Rev 10/20

Dietary Supplement

## with 100% Bioactive Folate

ENTERIC COATED, WELL TOLERATED, AND EASY TO SWALLOW.

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

#### **OBTREX DHA Combo Pack**

#### DOSAGE AND ADMINISTRATION:

Take one caplet and one softgel daily or as directed by your healthcare provider.

#### **HOW SUPPLIED:**

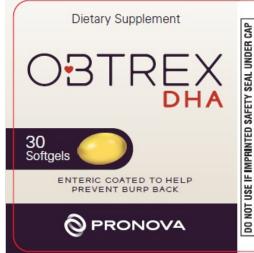
**OBTREX™ DHA:** is available as a combination pack, which contains: Bottle of 30 DHA translucent soft gels and a Bottle of 30 orange, oval shaped tablets with imprinted "OBX" Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat, light and moisture.

Dietary Supplement

THE SMALL, WELL-TOLERATED PRENATAL DUO FORMULATED TO ENSURE COMPLIANCE.†

Manufactured in the USA for: Pronova Corporation Miami, Florida 33155

#### KIT COMPONENTS LABELS



Supplement Facts Serving Size: 1 Soffgel / Servings Per Container: 30 IS BROKEN OR MISSING.

350 mg

DHA (docosahexaenoic acid)

% Daily Value not established.

Purified Water OTHER INGREDIENTS: Gelatin, Glycerine, Stearic Acid.

Sodium Alginate, purified fish oil.

OBTREXTM DHA Omega-3 Fatty Acids are manufactured under cGMP, CFIA and HACCP standards and are also in compliance with the Global Organization of DHA Omega-3 pregnancy and during the postnatal period for both lactating combination pack is indicated to provide vitamin and mineral supplementation throughou in improving nutritional status non-lactating mothers. **OBTREX**\*\* **DHA** is also useful in improving nutritit rto conception. INDICATIONS: OBTREXTM DHA standards.

Lot # & Exp. Date:

PEEL HERE FOR MORE INFORMATION

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

# Supplement Facts

Serving Size: 1 Softgel / Servings Per Container: 30

Amount % Daily Per Serving Value

DHA (docosahexaenoic acid) 350 mg

\* % Daily Value not established.

OTHER INGREDIENTS: Gelatin, Glycerine, Purified Water, Sodium Alginate, Stearic Acid. This product contains purified fish oil.

OBTREX™ DHA Omega-3 Fatty Acids are manufactured under cGMP, CFIA and HACCP standards and are also in compliance with the Global Organization of DHA Omega-3 standards.

INDICATIONS: OBTREX™ DHA combination pack is indicated to provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period for both lactating and non-lactating mothers. OBTREX™ DHA combination pack is also useful in improving nutritional status prior to conception.

Lot # & Exp. Date

†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.

DOSAGE AND ADMINISTRATION: One softgel daily; before, during and after pregnancy, with or without food, or as directed by a physician.

PRECAUTIONS: Ingestion of more than 3 grams per day of omega-3 fatty acids, such as DHA (docosahexaenoic acid) has been shown to have potential anti-thrombotic effects, including increased bleeding times. Administration of OBTREX™ DHA Omega-3 Fatty Acids should be avoided in patients taking anticoagulants.

Sold in combination with OBTREX™ DHA Prenatals

STORAGE: Store at room temperature, USP

Keep out of the reach of Children

To report a serious adverse event or to obtain product information, contact (866) 703-3508.

Code# PR0148-30DHAL Rev 10/20

Manufactured in the USA for:



**Pronova Corporation** Miami, Florida 33155



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1	00 NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.
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	- IMPRINT IS BROKEN
	USE
	NOT
	00

t s	Value***	100%	%29	43%	214%	213%	111%	2000%	283%	429%	107%	8%	192%	93%	
t Facts Container: 30	Per Serving 310 mcg	120 mg	10 mcg	state) 8.1 mg	3 mg	3.4 mg	20 mg	40 mg	. 1700 mcg D/E (1000 mcg Folic Acid)	12 mcg	29 mg	30 mg	25 mg	65mcg	ctating Women
Supplement Fa	Vitamin A (as Beta Carotene)	Vitamin C (as Ascorbic Acid)	Vitamin D (as Cholecalciferol)	Vitamin E (as dl-Alpha Tocopheryl Acetate)	Thiamin (as Thiamine HCI)	Riboflavin	Niacin (as Niacinamide)	Vitamin B6 (as Pyridoxine HCI)	Folate (as L-5-Methyl tetrahydro- folate Calcium) (1000	Vitam in B12 (as Cya nocoba lam in)	Iron (as Carbonyl Iron)	Magnesium (as Magnesium Oxide)	Zinc (as Zinc 0xide)	Selenium (as Sodium Selenate)	* Daily Value (DV) for Pregnan tand Lactating Women.

OTHER INGREDIENTS: Microcrystalline Cellulose. Methacrylic Acid Copolymer, Croscarmellose Sodium, Gebtin, Shearic Acid, Hyromellose, Mathodextin, Crospovidone, Starch, Salica, Titanium Dioxde, tracetin, Sucrose, Citric Per Acid, Magnesium Stearate, Sodium Lauryl Sulfate, Prolymyntyrrolicione, Sod Polysaccharide, Mineral Oli, Riboffavin, FD&C Yellow #6 Lake, Sodium Resonance, Trical clum Phosphate, Glycarol Monostearate, Trical clum Phosphate, Glycarol Monostearate, Trical clum Phosphate, Glycarol Monostearate, Trical pul Citrale, Ascorbly Palmitate, Triglycerides, Sodium Benzoate, Polysorbate 80, Sorbic Acid and Talc. Contains soy.

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP
IS BROKEN OR MISSING.

# Supplement Facts

Serving Size: 1 Caplet / Servings Per Container: 30

Serving Size: 1 Capiet / Servings Per Col	itainer: 30	
	Amount Per Serving	% Daily Value**
Vitamin A (as Beta Carotene)	810 mcg	62%
Vitamin C (as Ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg	67%
Vitamin E (as dl-Alpha Tocopheryl Aceta	te) 8.1 mg	43%
Thiamin (as Thiamine HCI)	3 mg	214%
Riboflavin	3.4 mg	213%
Niacin (as Niacinamide)	20 mg	111%
Vitamin B6 (as Pyridoxine HCI)	40 mg	2000%
	00 mcg DFE g Folic Acid)	283%
Vitamin B12 (as Cyanocobalamin)	12 mcg	429%
Iron (as Carbonyl Iron)	29 mg	107%
Magnesium (as Magnesium Oxide)	30 mg	8%
Zinc (as Zinc Oxide)	25 mg	192%
Selenium (as Sodium Selenate)	65mca	93%

**DESCRIPTION: OBTREX**<sup>TM</sup> **DHA** combination pack is indicated to provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period for both lactating and non-lactating mothers.

**OBTREX™ DHA** combination pack is also useful in improving nutritional status prior to conception.†

†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.

Daily Value (DV) for Pregnant and Lactating Women.

OTHER INGREDIENTS: Microcrystalline Cellulose, Methacrylic Acid Copolymer, Croscarmellose Sodium, Gelatin, Stearic Acid,

Hypromellose, Maltodextrin, Crospovidone, Starch, Silica, Titanium Dioxide, Triacetin, Sucrose, Citric Acid, Magnesium Stearate, Sodium Lauryl Sulfate, Polyvinylpyrrolidone, Soy Polysaccharide, Mineral Oil, Riboflavin, FD&C Yellow #6 Lake, Sodium Ascorbate, Polyethylene Glycol, Trisodium Citrate, Tocopherols, Tricalcium Phosphate, Glycerol Monostearate, Triethyl Citrate, Ascorbyl Palmitate, Triglycerides, Sodium Benzoate, Polysorbate 80, Sorbic Acid and Talc. Contains soy.

PEEL HERE FOR MORE INFORMATION

**DOSAGE AND ADMINISTRATION:** One caplet daily or as directed by a physician.

**CONTRAINDICATIONS: OBTREX**<sup>TM</sup> **DHA** is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

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

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B-12 is deficient

PRECAUTIONS: Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

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

STORAGE: Store at room temperature, USP.

Keep out of the reach of Children

To report a serious adverse event or to obtain product information, contact (866) 703-3508.

Code# PRO148-30PNL Rev 10/20

Manufactured in the USA for:



Pronova Corporation Miami, Florida 33155





#### **OBTREX DHA COMBO PACK**

docosahexaenoic acid, beta carotene, ascorbic acid, cholecalciferol, dl-alpha tocopheryl acetate, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, l-5-methyltetrahydrofolate calcium, cyanocobalamin, carbonyl iron, magnesium oxide, zinc oxide, sodium selenate kit

#### **Product Information**

Product Type DIETARY SUPPLEMENT Item Code (Source) NHRIC:67555-143

## **Packaging**

#	Item Code	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:67555-143-60	1 in 1 BOX		

## **Quantity of Parts**

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

# Part 1 of 2

# **OBTREX DHA SOFTGEL**

docosahexaenoic acid capsule, liquid filled

## **Product Information**

**Route of Administration** O

ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	350 mg

Inactive Ingredients							
Ingredient Name	Strength						
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)							
GLYCERIN (UNII: PDC6A3C0OX)							
WATER (UNII: 059QF0KO0R)							
SODIUM ALGINATE (UNII: C269C4G2ZQ)							
STEARIC ACID (UNII: 4ELV7Z65AP)							
FISH OIL (UNII: XGF7L72M0F)							

Pa	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1		30 in 1 BOTTLE		

Marketing Information									
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
dietary supplement		04/24/2023							

# Part 2 of 2

# **OBTREX DHA CAPLET**

beta carotene, ascorbic acid, cholecalciferol, dl-alpha tocopheryl acetate, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, l-5-methyltetrahydrofolate calcium, cyanocobalamin, carbonyl iron, magnesium oxide, zinc oxide, sodium selenate tablet, film coated

<b>Product Information</b>	
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	810 ug		
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg		
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug		
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL UNII:7QWA1RIO01)	.ALPHATOCOPHEROL, DL-	8.1 mg		
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	3 mg		
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	3.4 mg		
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg		
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE HYDROCHLORIDE	40 mg		
<b>LEVOMEFOLATE CALCIUM</b> (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1000 ug		
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug		
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	29 mg		
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	30 mg		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg		
SODIUM SELENATE (UNII: 5DQP25600A) (SELENATE ION - UNII:6X37R1DB70)	SELENIUM	65 ug		

Inactive Ingredients			
Ingredient Name	Streng	gth	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYME	R (1:1) (UNII: 74G4R6TH13)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)			
STARCH, RICE (UNII: 4DGK8B7I3S)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
TRIACETIN (UNII: XHX3C3X673)			
SUCROSE (UNII: C151H8M554)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)			
SOYBEAN COTYLEDON CELL WALL POLYSACCHARIDES (UN	II: 4UL6DF56YQ)		
MINERAL OIL (UNII: T5L8T28FGP)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
SODIUM ASCORBATE (UNII: S033EH8359)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
TOCOPHEROL (UNII: R0ZB2556P8)			
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)			

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBIC ACID (UNII: X045WJ989B)	
TALC (UNII: 7SEV7J4R1U)	

Pa	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1		30 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/24/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/24/2023	

# Labeler - Pronova Corporation (111421496)

Revised: 2/2023 Pronova Corporation