

TRICARE PRENATAL DHA ONE- fish oil, doconexent, icosapent, thiamine mononitrate, riboflavin, inositol niacinate, pyridoxine hydrochloride, cyanocobalamin, folic acid, ascorbic acid, cholecalciferol, d-alpha-tocopherol, biotin, ferrous fumarate, zinc sulfate monohydrate, cupric sulfate anhydrous, docusate sodium capsule, gelatin coated

Medecor Pharma, LLC

Reference Label Set Id: 6464712a-b1a5-439f-88f4-49de1742f22f

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](#).

TRICARE PRENATAL DHA ONE

Description:

Each purple softgel contains :

Essential Fatty Acids

Fish Oil Concentrate 10/50 TG	500 mg
DHA	215 mg
EPA	45 mg

Vitamins

Vitamin B-1 (Thiamine Nitrate)	3 mg
Vitamin B-2 (Riboflavin)	3.4 mg
Vitamin B-3 (Inositol Nicotinate)	20 mg
Vitamin B-6 (Pyridoxine Hydrochloride)	25 mg
Vitamin B-12 (Cyanocobalamin)	100 mcg
Folic Acid	1 mg
Vitamin C (Ascorbic Acid)	60 mg
Vitamin D3 (Cholecalciferol)	800 IU
Vitamin E (d-alpha-Tocopherol)	30 IU
Biotin	300 mcg

Minerals

Iron (Ferrous Fumarate)	27 mg
Zinc (Zinc Sulfate Monohydrate)	10 mg
Copper (Cupric Sulfate Anhydrous)	2 mg
Docusate Sodium	25 mg

INACTIVE INGREDIENTS:

Gelatin, Glycerol, Hydrogenated Vegetable Oil, Purified Water, Yellow Beeswax, Lecithin, Colloidal Anhydrous Silica, Ethanol, Natural Lime Oil Ordinary 479208/ARTG 1258, Cochineal C175470, Lemon Oil, Titanium Dioxide, Polysorbate 80, Brilliant Blue FCF C142090

CONTRAINDICATIONS:

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

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.

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 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

ADVERSE REACTIONS:

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

DOSAGE AND ADMINISTRATION:

One softgel daily or as directed by a physician.

HOW SUPPLIED:

TriCare Prenatal™ DHA ONE® Multivitamin/Mineral Softgels for oral administration are supplied as purple softgels, imprinted in gray ink: TriCare DHA 401 in a child-resistant plastic bottle of 30 softgels. (NDC 67112-401-30).

WARNING:

Ingestion of more than 3 grams of Omega-3 fatty acids (such as DHA) 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.

NOTICE: Contact with moisture may produce surface discoloration or erosion of the softgel.

Store at controlled room temperature of: 20°-25°C (68°-77°F).

Excursions permitted to 15°-30°C (59°-86°F).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Marketed by Medecor Pharma LLC, Baton Rouge, LA

TriCare Prenatal™
DHA ONE®

Multivitamin/Mineral
Softgel

ESSENTIAL NUTRITION FOR THE THREE
VITAL STAGES OF PREGNANCY

■ Preconception ■ Pregnancy ■ Postnatal

NDC 67112-401-30 Rx Only

TriCare Prenatal™ DHA ONE® Softgel www.DHAONE.com

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Vitamin B-12 (Cyanocobalamin)	100 mcg
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Vitamin C (Ascorbic Acid)	60 mg
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INDICATIONS AND USAGE: TriCare Prenatal™ DHA ONE® Multivitamin/Mineral softgels are indicated to provide multivitamin/mineral/essential fatty acid supplementation throughout pregnancy and during the postnatal period for both the lactating and non-lactating mother. It is also useful for improving nutritional status prior to conception.

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

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Marketed by Medecor Pharma LLC, Baton Rouge, LA

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Lot: Exp:

TRICARE PRENATAL DHA ONE

fish oil, doconexent, icosapent, thiamine mononitrate, riboflavin, inositol niacinate, pyridoxine hydrochloride, cyanocobalamin, folic acid, ascorbic acid, cholecalciferol, d-alpha-tocopherol, biotin, ferrous fumarate, zinc sulfate monohydrate, cupric sulfate anhydrous, docusate sodium capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67112-401
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FISH OIL (UNII: XGF7L72M0F) (FISH OIL - UNII:XGF7L72M0F)	FISH OIL	500 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	215 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	45 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE MONONITRATE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
INOSITOL NIACINATE (UNII: A99MK953KZ) (INOSITOL NIACINATE - UNII:A99MK953KZ)	INOSITOL NIACINATE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	100 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	800 [IU]
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	30 [IU]
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	27 mg
ZINC SULFATE MONOHYDRATE (UNII: PTX099XSF1) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 mg
CUPRIC SULFATE ANHYDROUS (UNII: KUW2Q3U1VV) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	25 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALCOHOL (UNII: 3K9958V90M)	
LIME OIL (UNII: UZH29XGA8G)	
COCHINEAL (UNII: TZ8Z31B35M)	
LEMON OIL (UNII: I9GRO824LL)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	purple	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	TriCare;DHA;40 1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67112-401-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2012	
2	NDC:67112-401-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2012	

Labeler - Medecor Pharma, LLC (830621046)

Registrant - Medecor Pharma, LLC (830621046)