NESTABS DHA PRENATAL MULTI-VITAMIN/MINERAL SUPPLEMENT WITH DHA/EPA- sodium ascorbate, cholecalciferol, di-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hcl, folic acid, cyanocobalamin, calcium formate, calcium carbonate, ferrous (ii) bis-glycinate chelate, potassium iodide, zinc oxide, choline bitartrate, with doconexent and icosapent

#### WOMENS CHOICE PHARMACEUTICALS 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.

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#### **NESTABS DHA Prenatal Multi-vitamin/Mineral Tablet**

**D escripton:** Nestabs DHA combination tablet-capsule for oral administration is a light pink capsule-shaped film coated tablet with a pleasant sweet flavor with WCOO1 imprinted on one side of the tablet and a enteric coated light amber soft gel capsule omega-3 fatty acid containing both DHA and EPA.

I ndications and Usage: Nestabs DHA is indicated to provide vitamin/mineral and omega-3 fatty acid supplementation to women throughout pregnancy, during the postnatal for both lactating and nonlactating mothers. Nestabs DHA is also beneficial in improving the nutritional status of women prior to conception.

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

**W arnings:** Ingestion of more than 3 grams of omega-fatty acids per day has been shown to have potential antithrombotic effects, including increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient.

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.

**P recautions:** Folic acid in doses above 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. This product contains formate, which if consumed above the recommended level, could cause visual impairment and other health effects. Do not take more than the recommended amount. If you are pregnant, nursing, or taking any medications consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

A dverse Reactions: Allergic sensitization has been reported following both oral and

parenteral administration of folic acid.

**D** osage and Administration: Nestabs DHA - One tablet and one soft gel capsule daily or as directed by a physician.

**H ow Supplied:** Nestabs DHA tablets for oral administration are supplied as six childresistant blister cards containing 5 tablets and 5 softgel capsules each (NDC# 50967-317-30).



# NESTABS DHA PRENATAL MULTI-VITAMIN/MINERAL SUPPLEMENT WITH DHA/EPA

sodium ascorbate, cholecalciferol, di-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hcl, folic acid, cyanocobalamin, calcium formate, calcium carbonate, ferrous (ii) bis-glycinate chelate, potassium iodide, zinc oxide, choline bitartrate, with doconexent and icosapent kit

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50967-317	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50967-317-30	4 in 1 CARTON	02/01/2011	
1		1 in 1 BLISTER PACK		

Quanti	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1		30		
Part 2		30		

#### Part 1 of 2

### **NESTABS MULTI-VITAMIN/MINERAL SUPPLEMENT**

sodium ascorbate, cholecalciferol, di-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hcl, folic acid, cyanocobalamin, calcium formate, calcium carbonate, ferrous (ii) bis-glycinate chelate, potassium iodide, zinc oxide, choline bitartrate tablet

#### **Product Information**

Route of Administration

ORAL

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE ION	3 mg
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	50 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
CALCIUM FORMATE (UNII: NP3JD65NPY) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	155 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII: 2M83C4R6ZB)	CALCIUM CATION	45 mg
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	32 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	450 [iU]
<b>ALPHA-TOCOPHERYLQUINONE</b> (UNII: ZO763K43XR) (ALPHA-TOCOPHERYLQUINONE - UNII: ZO763K43XR)	ALPHA- TOCOPHERYLQUINONE	30 [iU]
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	100 ug
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 mg
CHOLINE BITARTRATE (UNII: 6K2W7T9V6Y) (CHOLINE - UNII:N91BDP6H0X)	CHOLINE	55 mg

Inactive Ingredients	
Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI2606933)	
SACCHARIN (UNII: FST467XS7D)	

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	WC;001
Contains			

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
unapproved drug other		02/01/2011	

#### Part 2 of 2

#### **NESTABS OMEGA 3-DHA**

doconexent and icosapent supplement capsule, gelatin coated

#### **Product Information**

**Route of Administration** ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DOCONEXENT</b> (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	230 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	30 mg
.ALPHATOCOPHEROL, D- (UNII: N9PR3490H9) (.ALPHATOCOPHEROL, DUNII:N9PR3490H9)	.ALPHA TOCOPHEROL, D-	2 [iU]

## **Inactive Ingredients**

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

#### **Product Characteristics**

i i dual distributes			
Color	yellow	Score	no score
Shape	OVAL	Size	6mm
Flavor		Imprint Code	;
Contains			

## **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
unapproved drug other		02/01/2011	

Date

## **Marketing Information**

**Application Number or Monograph Marketing Start Marketing End** Marketing Citation Category Date

unapproved drug other	02/01/2011	

## Labeler - WOMENS CHOICE PHARMACEUTICALS LLC (833067841)

## **Registrant - WOMENS CHOICE PHARMACEUTICALS LLC (833067841)**

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
Women's Choice Pharmaceuticals		833067841	label(50967-317)			

Revised: 1/2023 WOMENS CHOICE PHARMACEUTICALS LLC