NESTABS ONE- vitamin c, vitamin d, vitamin e, vitamin b6, folate, vitamin b12, iron, zinc, magnesium, dha capsule, gelatin coated 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.

Nestabs One

DESCRIPTION: Nestabs® One is a prescription prenatal multi-vitamin/mineral in the form of a purple, opaque softgel capsule imprinted "ONE" for oral administration.

Each NESTABS® ONE Softgel contains:

Vitamin C (as calcium ascorbate) 18 mg
Vitamin D (as cholecalciferol) 6.25 mcg
Vitamin E (as d-alpha tocopheryl acetate) 10 mg
Vitamin B6 (as pyridoxine HCl) 30 mg
Folate (as (6S)-5 1 mg DFE*
-methyltetrahydrofolate -Quatrefolic®) ‡
Vitamin B12 (as cyanocobalamin) 15 mcg
Iron (as carbonyl iron and ferrous 38 mg

bis-glycinate chelate -Ferrochel®) ‡‡

Zinc (as zinc oxide) 20 mg

Magnesium (as magnesium oxide) 15 mg

DHA (Docosahexaenoic Acid from Algal Oil) 225 mg

*Dietary Folate Equivalent (DFE)

Other Ingredients: Gelatin capsule (bovine gelatin, glycerin, purified water, titanium dioxide, FD&C Red #40, FD&C Blue #1), soy lecithin, docusate sodium, white beeswax. Contains Soy.

INDICATION AND USAGE: Nestabs® One is a prescription prenatal multivitamin/mineral supplement with DHA that can be taken throughout pregnancy and during the postnatal period for both lactating and non-lactating mothers. Nestabs® One may also be useful in improving the nutritional status of women prior to conception. The usual dose is one softgel daily, or as directed by a physician.

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 years of age. **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN**. In case of accidental overdose, call a doctor or poison control center immediately

WARNINGS: Ingestion of more than 3 grams of omega-3 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.

PRECAUTIONS: Folic acid in doses above 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

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

DOSAGE AND ADMINISTRATION: One softgel taken orally each day, or as directed by a physician.

STORAGE: Store between 15-30°C (59°-86°F). Protect from extreme temperatures. Freezing & excessive heat may damage softgels.

HOW SUPPLIED: Nestabs® One softgels for oral administration are supplied in child resistant bottles containing 30 softgels, Item 50967-410-30 and as professional samples, Item 50967-410-03.

Rx

To report a serious adverse event or obtain product information, contact 1-800-664-1490.

Distributed By: Womens Choice Pharmaceuticals, LLC Berwyn, PA 19312 www.wcpharma.com

Nestabs® is a registered trademark of Womens Choice Pharmaceuticals, LLC ‡ Quatrefolic® under exclusive license from Gnosis, S.p.A covered by U.S. Patent No. 7,947,662 and patents pending PCT/EP2008/052037 and PCT/EP2008/052034 ‡‡ Ferrochel® is a registered trademark of Albion Laboratories, Inc., covered by U.S. Patents 6,716,814 and 7,838,042.

Outside/Visible Label

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Nestabs® is a registered trademark of Womens Choice Pharmaceuticals, LLC
Platmaceuticals, LLC
Pouterfolic* under exclusive license from Gnosis, S.p.A
covered by U.S. Patent No. 7.947.662 and patents pending
PCT/EP2080/052037 and PCT/EP2080/052034
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Laboratories, Inc., covered by U.S. Patents 6,716,814 and
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NSTONE 06/2017





- Small & Easy to Swallow Softgels
- Contains Vital Vitamins
 & Minerals Including
 Folate, Iron and DHA



30 Softgels **DIETARY SUPPLEMENT**

R_x Only

1/wa

Supplement Facts Serving Size: 1 Softgel / Servings Per Container: 30 Amount Per Serving Vitamin C (as calcium ascorbate) 18 mg 15% Vitamin D (as cholecalciferol) 6.25 mca 42% Vitamin E (as d-alpha tocopheryl acetate) 10 mg Vitamin B6 (as pyridoxine HCI) 30 mg 1500% Folate (as (6S)-5 1 -methyltetrahydrofolate -Quatrefolic®) ‡ 1 mg DFE* 167% 15 mcg 536% Vitamin B12 (as cyanocobalamin) Iron (as carbonyl iron and ferrous 38 mg 140% bis-glycinate chelate -Ferrochel®) ## Zinc (as zinc oxide) Magnesium (as magnesium oxide) 15 mg 4%

*Dietary Folate Equivalent (DFE). **Daily Value (DV) not established

Other Ingredients: Gelatin capsule (bovine gelatin, glycerin, purified water, titanium dioxide, FD&C Red #40, FD&C Blue #1), soy lecithin, docusate sodium, white beeswax. Contains Soy.

DHA (Docosahexaenoic Acid from Algal Oil) 225 mg

Inside Contents of Label

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NSTONE 06/2017

NESTABS ONE

vitamin c, vitamin d, vitamin e, vitamin b6, folate, vitamin b12, iron, zinc, magnesium, dha capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50967-410
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Route of Administration ORAL

Active Ingredient/Active Moiety

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Active ingredient/Active Molecy				
Ingredient Name	Basis of Strength	Strength		
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	38 mg		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1 mg		
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg		
ANTAZOLINE (UNII: DHA8014SS1) (ANTAZOLINE - UNII:DHA8014SS1)	ANTAZ OLINE	225 mg		
TOCOPHEROL (UNII: R0ZB2556P8) (TOCOPHEROL - UNII:R0ZB2556P8)	TOCOPHEROL	10 mg		
CALCIUM ASCORBATE (UNII: 183E4W213W) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	18 mg		
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug		
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	15 mg		
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	6.25 ug		
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	30 mg		

Inactive Ingredients	
Ingredient Name	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
WHITE WAX (UNII: 7G1J5DA97F)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	purple (Opaque)	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	ONE
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:50967-410-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2017	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug		07/20/2017	
other			

Labeler - Womens Choice Pharmaceuticals, LLC (833067841)

Revised: 4/2022 Womens Choice Pharmaceuticals, LLC