NEONATAL DHA- vitamin c, calcium, iron, vitamin d3, vitamin e, thiamin, riboflavin, niacinamide, vitamin b6, folic acid, iodine, zinc, copper, docusate sodium tablet
SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS

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.

NEONATAL DHA

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.

DESCRIPTION

Neonatal DHA is a prescription prenatal/postnatal multi-vitamin/mineral tablet and a soft gel of DHA an essential fatty acid.

Each tablet contains:	
VITAMIN A (AS BETA CAROTENE)	1200 MCG
VITAMIN C (ASCORBIC ACID)	120 MG
VITAMIN D3 (AS CHOLECALCIFEROL)	25 MCG
VITAMIN E (AS DL-ALPHA TOCOPHEROL ACETATE)	18.4 MG
VITAMIN B1 (AS THIAMINE MONONITRATE)	3 MG
VITAMIN B2 (AS RIBOFLAVIN)	3 MG
VITAMIN B3 (AS NIACINAMIDE)	20 MG
VITAMIN B6 (AS PYRIDOXINE HCL)	3 MG
FOLIC ACID	1000 MCG
VITAMIN B12 (AS CYANOCOBALAMIN)	8 MCG
CALCIUM (AS CALCIUM CARBONATE)	200 MG
IRON (AS FERROUS FUMARATE)	29 MG
ZINC (AS ZINC OXIDE)	15 MG
COPPER (AS CUPRIX OXIDE)	3 MG
BIOTIN	30 MCG
PANTOTHENIC ACID (AS CALCIUM-D- PANTOTHENATE	7 MG
MAGNESIUM (AS MAGNESIUM OXIDE)	100 MG
IODINE (AS POTASSIUM IODIDE)	150 MCG

Other Ingredients: microcrystalline cellulose, stearic acid, croscarmellose sodium, silicon dioxide, magnesium stearate, HPMC E15, HPMC E5/E6,titanium dioxide,PEG-8000,

Each DHA soft gel contains:	
Algal oil	500 mg
Docosahexaenoic Acid (DHA,) Algal Oil)	200 mg

Other ingredients in DHA soft gel: Gelatin,Glycerin,Purified water

INDICATIONS

NEONATAL DHA is a multi-vitamin/mineral prescription drug indicated for use in improving the

nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

CONTRAINDICATIONS

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

WARNING

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including an 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.

WARNING: 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 progress.

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

One tablet and one capsule daily or as directed by a physician.

STORAGE

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimalized.

NOTICE: Contact with moisture can discolor or erode the tablet.

HOW SUPPLIED

30 Prenatal DHA Soft Gels & 30 Prenatal Vitamin - **NDC** 73317-6288-6.

To report a serious adverse event or obtain product information, call 1-866-760-6565.

Please consult your health care provider with any dietary concerns.

DHA soft gels manufactured for:

Call your licensed medical practitioner about side effect.

Manufactured for and Distributed by:

AUM Pharmaceuticals
Hauppauge, NY 11788.

Made in USA

NEONATAL DHA

vitamin c, calcium, iron, vitamin d3, vitamin e, thiamin, riboflavin, niacinamide, vitamin b6, folic acid, iodine, zinc, copper, docusate sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73317-6288
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BETA CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	1200 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	25 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	18.4 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	3 mg

FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	8 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	29 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	3 mg
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	30 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	100 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug

Inactive Ingredients

Ingredient Name	Strength
SCHIZOCHYTRIUM DHA OIL (UNII: 2GQR19D8A4)	500 mg
4,7,10,13,16,19-DOCOSAHEXAENOIC ACID, (4E,7E,10E,13E,16E,19E)- (UNII: ZR7NX0Z98X)	200 mg
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
TALC (UNII: 7SEV7J4R1U)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE	**Size**	6mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73317-6288-6	2 in 1 CARTON	09/15/2020	
1		30 in 1 BOTTLE		
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/15/2020	

Labeler - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

Registrant - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

Establishment

Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS		081225162	manufacture(73317-6288)