

NEONATAL19- ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cyanocobalamin, biotin, pantothenic acid 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 19

WARNING: If you are pregnant, nursing or taking medication, consult your doctor before use. Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. In case of accidental overdose, call a doctor or Poison Control Center immediately.

DESCRIPTION

NEONATAL 19 is a prescription prenatal vitamin with folic acid. Other vitamins and minerals for nutritional supplementation NEONATAL 19 is a small, round, tablet

Each tablet contains:

Vitamin C (Ascorbic Acid)	100 mg
Vitamin B1 (Thiamine)	1.5 mg
Vitamin B2 (Riboflavin)	1.7 mg
Vitamin B3 (Niacinamide)	20 mg
Vitamin B6 (Pyridoxine HCl)	10 mg
Folic Acid	1000 mcg
Vitamin B12 (Cyanocobalamin)	6 mcg
Biotin	150 mcg
Pantothenic Acid	5 mg

Inactive ingredients:

Microcrystalline Cellulose, Di Calcium Phosphate, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Opadry II Yellow (color).

INDICATIONS

NEONATAL 19 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 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 THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS

Folic Acid

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 these products since folic acid may mask the symptoms of pernicious anemia.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Dosing for elderly patients should be cautious. Due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy, dosing should start at the lower end of the dosing range.

ADVERSE REACTIONS

Adverse reactions with iron therapy may include GI irritation, constipation, diarrhea, nausea, vomiting, and dark stools. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DRUG INTERACTIONS

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones.

OVERDOSAGE

Symptoms: abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hypotension, hypothermia, lethargy, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, tachycardia, hyperglycemia, drowsiness, pallor, cyanosis, lassitude, seizures, and shock.

DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

NOTICE Contact with moisture can discolor or erode the tablet. Do not chew tablet.

STORAGE

Store at 20°-25°C (66°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Protect from heat, light and moisture.

HOW SUPPLIED

Bottles of 100 tablets each - NDC 73317-8242-1

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

Call your licensed medical practitioner about side effect.

You may report side effects by calling AUM 866-760-6565.

Distributed by:

AUM Pharmaceuticals
Hauppauge, NY 11788.

Made in USA



EACH TABLET CONTAINS:
Serving Size: One(1) Tablet

Vitamin C (Ascorbic acid)	100 MG
Vitamin B1 (As Thiamine Mononitrate)	1.5 MG
Vitamin B2 (Riboflavin)	1.7 MG
Vitamin B3 (As Niacinamide)	20 MG
Vitamin B6 (As Pyridoxine HCl)	10 MG
Folic Acid	1000 MCG
Vitamin B12 (Cyanocobalamin) on DCP	6 MCG
Biotin on DCP	150 MCG
Pantothenic Acid	5 MG

OTHER INGREDIENTS
Microcrystalline Cellulose, Dicalcium Phosphate, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Opadry II Yellow.

DOSE AND ADMINISTRATION:
Before, during and/or after pregnancy, one tablet daily, with a meal, or as directed by a licensed healthcare practitioner regardless of lactation status.

CAUTION:
High levels of folic acid may, especially in older adults, hide signs of Vitamin B-12 deficiency (such as pernicious anemia), a condition that can cause nerve damage.

DESCRIPTION: Neonatal 19 is a prenatal vitamin with folic acid, other vitamins and minerals for nutritional supplementation.

WARNING: If you are pregnant, nursing or taking medication, consult your doctor before use. Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. In case of accidental overdose, call a doctor or Poison Control Center immediately.

See package insert for full prescribing information.

STORAGE: Store at 15°- 30°C (69°- 86°F) [See USP Controlled Room Temperature]. Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

KEEP OUT OF REACH OF CHILDREN.
DO NOT USE IF SEAL UNDER CAP IS BROKEN.

Call your licensed medical practitioner about side effect.
You may report side effects by calling **AUM 1-866-760-6565**

AUM PHARMACEUTICALS
Distributed by:
AUM Pharmaceuticals
Hauppauge, NY 11788
MADE IN USA
Rev: 08/20

NEONATAL19

ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cyanocobalamin, biotin, pantothenic acid tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73317-8242
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	6 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	150 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	5 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
OPADRY YS-1-12726A YELLOW (UNII: PLG7GLN7QI)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73317-8242-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/24/2020	

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(73317-8242)

Revised: 9/2020

SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS