

PRENATAL VITAMINS PLUS LOW IRON- prenatal with ferrous fum and folic acid tablet
Carilion Materials Management

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.

PRENATAL VITAMINS PLUS LOW IRON TABLETS

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Each Tablet Contains :	Amount Per Tablet	% Daily Value
Vitamin A (from Acetate and Beta Carotene)	4000 IU	80%
Vitamin C (Ascorbic Acid)	120 mg	200%
Vitamin D-3 (Cholecalciferol)	400 IU	100%
Vitamin E (dl-Alpha Tocopheryl Acetate)	22 mg	73%
Vitamin B-1(Thiamine Mononitrate)	1.84 mg	123%
Vitamin B-2 (Riboflavin)	3 mg	176%
Niacin (as Niacinamide)	20 mg	100%
Vitamin B-6 (Pyridoxine HCl)	10 mg	500%
Folic Acid	1 mg	200%
Vitamin B-12 (Cyanocobalamin)	12 mcg	200%
Calcium (from Calcium Carbonate)	200 mg	20%
Iron (Ferrous Fumarate)	27 mg	150%
Zinc (Zinc Oxide)	25mg	167%
Copper (Cupric Oxide)	2 mg	100%

Other Ingredients: Ascorbyl Palmitate, Citric Acid anhydrous, DL- alpha Tocopherol, Ethylcellulose, FD&C Blue #2 lake, FD&C Red #40 lake, FD&C Yellow #6 lake, Glucose, Gum Acacia, Hypromellose, Magnesium Stearate, Maize Starch, Maltodextrin, Methylcellulose, Microcrystalline Cellulose, Mineral Oil, Mono and di-glycerides, Polyethylene Glycol, Pregelatinized Corn Starch, Silicon Dioxide, Sorbic Acid, Soy Protein, Stearic Acid, Sucrose, Titanium Dioxide, Tricalcium Phosphate.

Indications: To provide Vitamin and Mineral supplementation throughout pregnancy and during the postnatal period for both the lactating and nonlactating mother. It is also useful for improving nutritional status prior to conception.

Directions: Before, during and after pregnancy, one tablet daily or as directed by a physician.

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

Caution: Folic Acid may partially correct the hematological damage due to Vitamin B-12 deficiency of pernicious anemia while the associated neurological damage progresses.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN. In case of accidental overdose, call a physician or Poison Control Center immediately.

Store at room temperature, USP. Dispense in a well closed light resistant container.

HOW SUPPLIED

Product: 68151-5878

NDC: 68151-5878-1 1 TABLET in a BLISTER PACK

PRENATAL VITAMINS PLUS LOW IRON (PRENATAL WITH FERROUS FUM AND FOLIC ACID) TABLET



PRENATAL VITAMINS PLUS LOW IRON

prenatal with ferrous fum and folic acid tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68151-5878(NDC:39328-106)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	3080 [iU]
.BETA.-CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	920 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	22 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.84 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	200 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	27 mg
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	25 mg
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	2 mg

Inactive Ingredients

Ingredient Name	Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
ACACIA (UNII: 5C5403N26O)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBIC ACID (UNII: X045WJ989B)	
SOY PROTEIN (UNII: R44IWB3RN5)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

Color	brown (Beige)	Score	no score
Shape	OVAL (OVAL)	Size	9mm
Flavor		Imprint Code	P;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68151-5878-1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		04/01/2013	

Labeler - Carilion Materials Management (079239644)

Establishment

Name	Address	ID/FEI	Business Operations
Carilion Materials Management		079239644	REPACK(68151-5878)

Revised: 12/2017

Carilion Materials Management