CITRANATAL BLOOM- iron, folic acid, cyanocobalamin, ascorbic acid, and docusate sodium tablet, film coated Mission Pharmacal Company

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.

CitraNatal Bloom

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:

CitraNatal Bloom TMis a prescription prenatal/postnatal multi-vitamin/mineral tablet with Ferr-Ease [®], a patented dual-iorn delivery comprising both a quick release and slow release iron. CitraNatal Bloom is a green, modified rectangle shaped, film-coated tablet, debossed with "CB" on one side and blank on the other.

Iron (Carbonyl iron, ferrous gluconate)	90	mg
Folic Acid	1	mg
Vitamin B ₁₂ (Cyanocobalamin)	12	mcg
Vitamin C (Ascorbic acid)	120	mg
Docusate sodium	50	mg

Inactive Ingredients:

Povidone, croscarmellose sodium, acrylic resin, color added, magnesium stearate, FD&C Yellow No. 5, magnesium silicate, FD&C Blue No. 1, polyethylene glycol, vitamin A palmitate, ethyl vanillin.

INDICATIONS

CitraNatal Bloom 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:

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemia 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 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 minimized.

NOTICE:

Contact with moisture can discolor or erode the tablet.

HOW SUPPLIED:

Bottles of 30 tablets each — (**NDC**0178-0813-30).

To report a serious adverse event or obtain product information, call (800) 298-1087.

MISSION PHARMACAL COMPANY, San Antonio, TX 78230 1355

CitraNatal Bloom Label



CITRANATAL BLOOM

iron, folic acid, cyanocobalamin, ascorbic acid, and docusate sodium tablet, film coated

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0178-0813	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	138 mg		
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	88.5 mg		
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	55 mg		
FERROUS GLUCONATE (UNII: U1B11I423Z) (FERROUS CATION - UNII: GW89581OWR)	FERROUS CATION	13.2 mg		
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.4 mg		
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	16.8 ug		

Inactive Ingredients				
Ingredient Name	Strength			
POVIDONE (UNII: FZ989GH94E)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
MAGNESIUM SILICATE (UNII: 9B9691B2N9)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)				
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)				
ETHYL VANILLIN (UNII: YC9ST449YJ)				

Product Characteristics				
Color	green	Score	no score	
Shape	RECTANGLE (modified rectangle)	Size	9mm	
Flavor		Imprint Code	СВ	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0178-0813-	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2017	06/01/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2017	06/01/2024

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927726893)

Establishment				
Name	Address	ID/FEI	Business Operations	
Mission Pharmacal Company		927726893	manufacture(0178-0813)	

Revised: 1/2024 Mission Pharmacal Company