INATAL ULTRA - inatal ultra tablet, coated
Nnodum 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.

INATAL Ultra

Prenatal Multivitamin/
Multimineral Tablets
63044-154-63

Rx Only

WARNING: Accidental overdose of iron-containing prod-Ucts 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:

INATAL Ultra is a white, dye free, oval oil-and-water-soluble multivitamin/multimineral tablet with calcium citrate and carbonyl iron.

Each tablet contains:

Vitamin A* . . . . . 2700 I.U.

Vitamin C (Ascorbic Acid) . . . . . 120 mg

Calcium (Calcium Citrate) . . . . . 200 mg

Elemental Iron (Carbonyl Iron) . . . . . 90 mg

Vitamin D3 (Cholecalciferol) . . . . . 400 I.U.

Vitamin E (dl-Alpha Tocopheryl Acetate) . . . . . 30 I.U.

Vitamin B1 (Thiamine Mononitrate) . . . . . 3 mg

Vitamin B2 (Riboflavin) . . . . . 3.4 mg

Niacinamide . . . . . 20 mg

Vitamin B6 (Pyridoxine HCI) . . . . . 20 mg

Folic Acid . . . . . 1 mg

Vitamin B12 (Cyanocobalamin) . . . . . 12 mcg

Iodine (Potassium Iodide) . . . . . 150 mcg

Zinc (Zinc Oxide) . . . . . 25 mg

Copper (Cupric Oxide) . . . . . 2 mg

Docusate Sodium . . . . . 50 mg

*Input as Vitamin A palmitate and beta carotene.

INDICATIONS:

INATAL Ultra ® is a multivitamin/multimineral nutritional supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. Ultra NatalCare® can also be beneficial in improving the nutritional status of women prior to conception.

CONTRAINDICATIONS:

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

WARNINGS:

Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient.

NOTICE: Contact with moisture may produce surface discoloration or erosion of the tablet.

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.

PEDIATRIC USE:

Safety and effectiveness in pediatric patients have not been established.

GERIATRIC USE:

Clinical studies on this product have not been performed in sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

DOSAGE AND ADMINISTRATION:

One tablet daily or as directed by a physician.

HOW SUPPLIED:

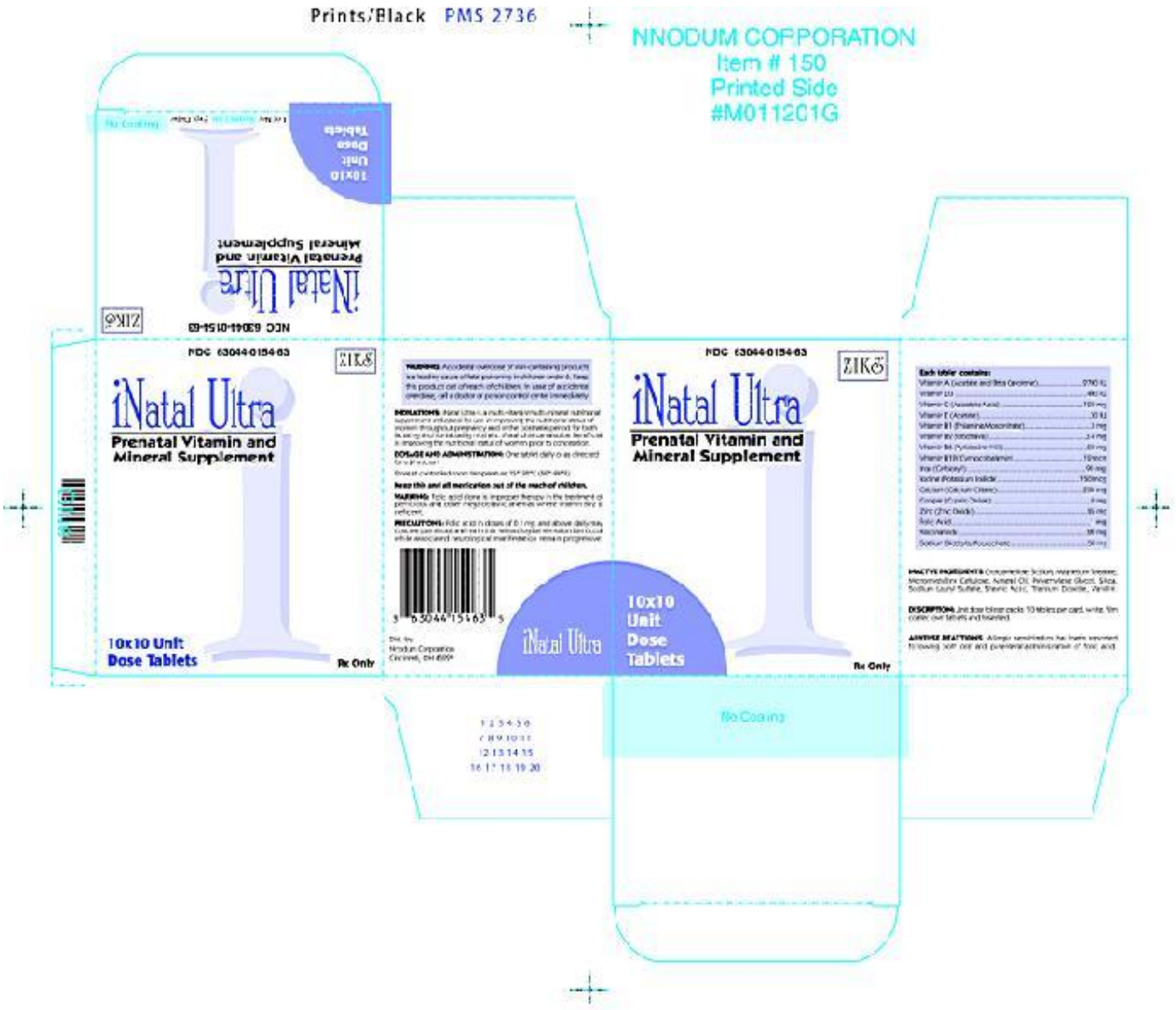
NDC 63044-154-63 Unit Dose Packs containing 10 tablets per card.

Store at controlled room temperature 15°-30°C (59°-86°F).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured for
Nnodum Pharmaceutical
Cincinnati, Ohio 45229

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



INATAL ULTRA

inatal ultra tablet, coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63044-154
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2700 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM CITRATE	200 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (IRON - UNII:E1UOL152H7)	IRON PENTACARBONYL	90 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (ALPHA-TOCOPHEROL - UNII:H4N855PNZ1)	ALPHA-TOCOPHEROL ACETATE	30 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)	THIAMINE MONONITRATE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	20 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM IODIDE	150 ug
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC - UNII:J41CSQ7QDS)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (COPPER - UNII:789U1901C5)	CUPRIC OXIDE	2 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
VANILLIN (UNII: CHI530446X)	

Product Characteristics

Color	WHITE (dye-free)	**Score**	2 pieces
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	cpc43
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:63044-154-63	10 in 1 BOX, UNIT-DOSE		
1		10 in 1 BLISTER PACK		
2	NDC:63044-154-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/20/2005	

Labeler - Nnodum Pharmaceuticals (960457273)

Revised: 10/2009 Nnodum Pharmaceuticals