

**INATAL ADVANCE - inatal advance 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.*

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**INATAL ADVANCE Tablet**  
**63044-153-64**

Prenatal multivitamin/multimineral tablet  
combining 15 vitamins and minerals,  
including calcium and carbonyl iron.

Rx Only

**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**

INATAL Advanced® is a white, dye-free, oval shaped, oil-and-water soluble multivitamin/multimineral tablet which contains calcium carbonate and carbonyl iron.

Each tablet contains:

- Vitamin A (as beta-carotene) . . . . . 2700 I.U.
- Vitamin C (ascorbic acid) . . . . . 120 mg
- Calcium (as calcium carbonate) . . . . . 200 mg
- Elemental Iron (as carbonyl iron) . . . . . 90 mg
- Vitamin D3 (cholecalciferol) . . . . . 400 I.U.
- Vitamin E (dl-alpha tocopheryl acetate) . . . . . 30 I.U.
- Vitamin B1 (as thiamine mononitrate) . . . . . 3 mg
- Vitamin B2 (riboflavin, USP) . . . . . 3.4 mg
- Niacinamide . . . . . 20 mg
- Vitamin B6 (as pyridoxine HCl, USP) . . . . . 20 mg
- Folic Acid, USP . . . . . 1 mg
- Vitamin B12 (cyanocobalamin) . . . . . 12 mcg
- Zinc (as zinc oxide, USP) . . . . . 25 mg
- Copper (as cupric oxide) . . . . . 2 mg
- Magnesium (as magnesium oxide, USP) . . . . . 30 mg
- Docusate Sodium . . . . . 50 mg

**INACTIVE INGREDIENTS:** Carnuba wax, crospovidone, ethyl vanillin, hydroxypropyl methylcellulose, magnesium stearate, polyethylene glycol, silicon dioxide, stearic acid, and titanium dioxide

**INDICATIONS:**

INATAL ADVANCE® 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. INATAL Advanced® 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 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

**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 63044-153-64 Unit Dose Packs of 90's with each blister card 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.**

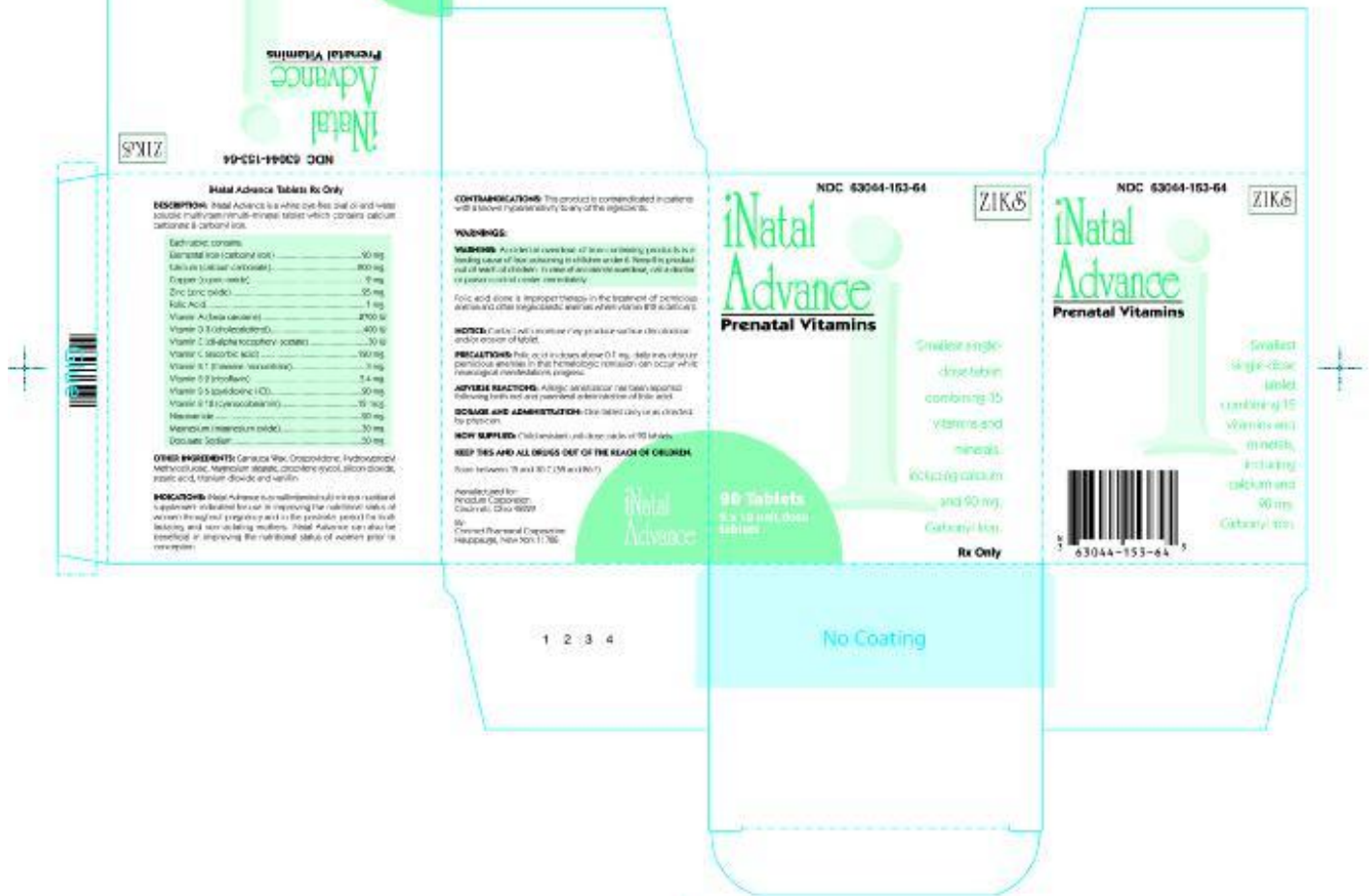
Manufactured For  
Nnodum Pharmaceuticals  
Cincinnati, Ohio 45229

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NNODUM

Item # 150  
Printed Side  
#M011201G

Printing Colors/ PMS 3278 Black



**90 Tablets**

**Net Weight: 1.50 g (0.053 oz)**

**Net Content: 90 Tablets**

**Lot No.:** \_\_\_\_\_  
**Exp. Date:** \_\_\_\_\_

**NDC 63044-153-64**

**Net Content: 90 Tablets**

**DESCRIPTION:** iNatal Advance is a white dye-free oval and water soluble multivitamin/mineral-tablet which contains calcium carbonate & carbonyl iron.

**Each tablet contains:**

Elemental Iron (carbonyl iron)	90 mg
Calcium (calcium carbonate)	200 mg
Copper (cupric oxide)	2 mg
Zinc (zinc oxide)	95 mg
Folic Acid	1 mg
Vitamin A (beta carotene)	2700 IU
Vitamin D 3 (cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Vitamin C (ascorbic acid)	120 mg
Vitamin B 1 (thiamine mononitrate)	3 mg
Vitamin B 2 (riboflavin)	3.4 mg
Vitamin B 6 (pyridoxine HCl)	20 mg
Vitamin B 12 (cyanocobalamin)	12 mcg
Niacinamide	20 mg
Magnesium (magnesium oxide)	30 mg
Docusate Sodium	50 mg

**OTHER INGREDIENTS:** Carnauba Wax, Croscopolone, Hydroxypropyl methylcellulose, Hypromellose, croscopolone glycol, silicon dioxide, stearic acid, titanium dioxide and vanillin.

**INDICATIONS:** iNatal Advance is indicated for use as a nutritional supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period. The suitability and use of this product should be determined by the physician and the nutritional status of women prior to conception.

**CONTRAINDICATIONS:** This product is contraindicated in women with a known hypersensitivity to any of the ingredients.

**WARNINGS:**

**WARNING:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Folic acid alone is inappropriate in the treatment of pernicious anemia and other megaloblastic anemias unless vitamin B12 is also given.

**NOTICE:** Careful use of caution is required when taking this product with other drugs.

**PRECAUTIONS:** Fully or partially absorbable iron may occur in patients with iron deficiency anemia. In that hematologic remission can occur while hematologic conditions persist.

**ADVERSE REACTIONS:** Allergic reactions have been reported following both oral and parenteral administration of this acid.

**DOSEAGE AND ADMINISTRATION:** One tablet daily or as directed by physician.

**HOW SUPPLIED:** One hundred and fifty (150) tablets.

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

Keep between 78 and 80°F (25 and 28°C).

Manufactured for:  
Nnodum Corporation  
Cincinnati, Ohio 45299  
90  
Chemical Pharmaceutical Corporation  
Hudsonville, Michigan 49421

**NDC 63044-153-64**

**ZIK'S**

**iNatal Advance**  
Prenatal Vitamins

Smallest single-dose combination of vitamins and minerals including calcium and 90 mg Carbonyl Iron

**90 Tablets**  
0.5 g (0.018 oz) per tablet

**Rx Only**

**NDC 63044-153-64**

**ZIK'S**

**iNatal Advance**  
Prenatal Vitamins

Smallest single-dose combination of vitamins and minerals including calcium and 90 mg Carbonyl Iron

**90 Tablets**  
0.5 g (0.018 oz) per tablet

**Rx Only**



63044-153-64

1 2 3 4

No Coating

**Exp. Date:** \_\_\_\_\_

**Lot No.:** \_\_\_\_\_

**3 63044 15301 0**

**Each tablet contains:**

Elemental Iron (carbonyl iron)	90 mg
Calcium (calcium carbonate)	200 mg
Copper (cupric oxide)	2 mg
Zinc (zinc oxide)	95 mg
Folic Acid	1 mg
Vitamin A (beta carotene)	2700 IU
Vitamin D 3 (cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Vitamin C (ascorbic acid)	120 mg
Vitamin B 1 (thiamine mononitrate)	3 mg
Vitamin B 2 (riboflavin)	3.4 mg
Vitamin B 6 (pyridoxine HCl)	20 mg
Vitamin B 12 (cyanocobalamin)	12 mcg
Niacinamide	20 mg
Magnesium (magnesium oxide)	30 mg
Docusate Sodium	50 mg

**INACTIVE INGREDIENTS:** carnauba wax, croscopolone, hydroxypropyl methylcellulose, magnesium stearate, propylene glycol, silicon dioxide, stearic acid, titanium dioxide and vanillin.

**DESCRIPTION:** iNatal Advance is a white dye-free oval and water soluble multivitamin/mineral-tablet which contains calcium carbonate & carbonyl iron.

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

**DISPENSE IN A TIGHT, LIGHT-RESISTANT CONTAINER WITH A CHILD RESISTANT CLOSURE.**

**DISPENSE IN A TIGHT, LIGHT-RESISTANT CONTAINER WITH A CHILD RESISTANT CLOSURE.**

**WARNING:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Distributed by: Nnodum Pharmaceuticals Cincinnati, OH 45299

**NDC 63044-153-01**

**ZIK'S**

**iNatal Advance**  
Prenatal Vitamins

**90 Tablets**

**Rx Only**

**INATAL ADVANCE**  
inatal advance tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:63044-153
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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 CARBONATE (UNII: H0G9379FGK) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM CARBONATE	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:KV2JZ1B16Z)	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
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC - UNII:J41CSQ7QDS)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (COPPER - UNII:789U1901C5)	CUPRIC OXIDE	2 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM - UNII:I38ZP9992A)	MAGNESIUM OXIDE	30 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPOVIDONE (UNII: 68401960MK)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	

**Product Characteristics**

<b>Color</b>	WHITE (dye-free)	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	cpc2859
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:63044-153-64	9 in 1 BOX, UNIT-DOSE		
1		10 in 1 BLISTER PACK		
2	NDC:63044-153-01	90 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/10/2005	

**Labeler** - Nnodum Pharmaceuticals (960457273)

### Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		057795122	MANUFACTURE

Revised: 10/2009

Nnodum Pharmaceuticals