PRENATAL VITAMINS PLUS- vitamin a, vitamin c, vitamin d-3, vitamin e, vitamin b-1, vitamin b-2, niacin, vitamin b-6, calcium, iron, zinc, copper tablet 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.

Prenatal Vitamins Plus - 150

PRENATAL VITAMINS PLUS LOW IRON

Supplemental Facts

| Each tablet Contains: | Amount per Tablet | % Daily Value |
|---|-------------------|---------------|
| Vitamin A (Acetate and Beta Carotene) | 4000 I.U. | 80% |
| Vitamin C (Ascorbic acid) | 120 mg | 200% |
| Vitamin D-3 (Cholecalciferol) | 400 I.U. | 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 (Niacinaminde) | 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) | 25 mg | 167% |
| Copper (Cupric Oxide) | 2 mg | 100% |

Other Ingredients:

Corn Starch, Dicalcium Phosphate, DL Alpha Tocopherol, FD&C: Blue #2 Lake, FD&C: Red #40 Lake, FD&C: Yellow #6 Lake, Gum Arabic, Hydroxypropyl Methylcellulose, Maltodextrin, Microcrystalline Cellulose, Modified food starch, Polyethylene Glycol (PEG), Polyvinyl Alcohol, Pregelatinized Starch, Silicon Dioxide, Sucrose, Talc, Titanium Dioxide.

Directions:

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

Caution:

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

Warning:

Accidental overdose of iron-containing products is a leading cause of fetal poisoning in children under six.

KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

In case of acciential overdose, call a physician or Poison Control Center immediately.

Indications:

To promote vitamin and mineral supplementation throughout pregnancy and during the postnatal period for both the lactating and non lactating mother. It is also useful for improving nutritional status prior to conception.

Contraindications:

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

Storage:

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

Safety Information:

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

Prenatal Vitamins Plus Low iron tablets product label

Rx Only NDC 63044-150-05

Prenatal Vitamins Plus Low iron tablets

Vitamins and Mineral Supplement for pregnant & lactating women

ZIKS Nnodum Pharmaceuticals

500 Tablets

Manufactured for: Nnodum Pharmaceuticals

Cincinnati, OH 45240 (513) 861-2329

MADE IN THE USA



63044-150-05

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MADE IN USA



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PRENATAL VITAMINS PLUS

vitamin a, vitamin c, vitamin d-3, vitamin e, vitamin b-1, vitamin b-2, niacin, vitamin b-6, calcium, iron, zinc, copper tablet

| Product Information | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:63044-150 |
| 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 | 4000 [iU] |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 120 mg |
| CHOLECALCIFEROL (UNII: 1C6 V77QF41) (CHOLECALCIFEROL - UNII:1C6 V77QF41) | CHOLECALCIFEROL | 400 [iU] |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0) (.ALPHATOCOPHEROL - UNII: H4N8 55PNZ1) | .ALPHATOCOPHEROL ACETATE | 22 mg |

| THIAMINE MONONITRATE (UNII: 8 K0 I0 49 19 X) (THIAMINE ION - UNII:4ABT0 J9 45J) | THIAMINE ION | 1.84 mg |
|---|-------------------|---------|
| RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR) | RIBOFLAVIN | 3 mg |
| NIACINAMIDE (UNII: 25X5118 RD4) (NIACINAMIDE - UNII:25X5118 RD4) | NIACINAMIDE | 20 mg |
| PYRIDO XINE HYDRO CHLO RIDE (UNII: 68 Y4CF58 BV) (PYRIDO XINE - UNII: KV2JZ1BI6Z) | PYRIDO XINE | 10 mg |
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 1 mg |
| CYANO COBALAMIN (UNII: P6 YC3EG204) (CYANOCOBALAMIN - UNII:P6 YC3EG204) | CYANOCOBALAMIN | 12 ug |
| $\textbf{CALCIUM CARBONATE} \ (\textbf{UNII: H0G9379FGK}) \ (\textbf{CALCIUM CATION - UNII: 2M83C4R6ZB})$ | CALCIUM CARBONATE | 200 mg |
| FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR) | FERROUS CATION | 27 mg |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 25 mg |
| COPPER (UNII: 789 U190 1C5) (COPPER - UNII:789 U190 1C5) | COPPER | 2 mg |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| ACACIA (UNII: 5C5403N26O) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) | |
| CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL (UNII: 532B59J990) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | |
| SUCROSE (UNII: C151H8M554) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | |

| Product Characteristics | | | | |
|-------------------------|----------------|--------------|----------|--|
| Color | orange (peach) | Score | no score | |
| Shape | OVAL | Size | 7mm | |
| Flavor | | Imprint Code | N150 | |
| Contains | | | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63044-150- 01 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/25/2016 | |
| 2 | NDC:63044-150- 05 | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 0 2/25/20 16 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 02/25/2016 | |
| | | | |

Labeler - Nnodum Pharmaceuticals (960457273)

Registrant - Nnodum Pharmaceuticals (960457273)

| Establishment | | | | |
|------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Nnodum Pharmaceuticals | | 960457273 | manufacture(63044-150) | |

Revised: 12/2019 Nnodum Pharmaceuticals