EMBRIVA- ascorbic acid, cholecalciferol, thiamine, pyridoxal phosphate, folic acid, methylcobalamin, calcium carbonate, ferrous gluconate, potassium iodide tablet

Oncora Pharma, LLC

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 Rx Only

DESCRIPTION

Each Tablet Contains:

Amount per Tablet

| Thiamine (Vitamin B-1) (from Thiamine Mononitrate) | 1.4 mg |
|--|---------|
| Ascorbic Acid | 125 mg |
| Folic Acid | 1 mg |
| Colecalciferol | 0125 mg |
| Pyridoxal Phosphate Anhydrous | 2.5 mg |
| Methylcobalamin | 1 mg |
| Calcium Carbonate | 200 mg |
| Ferrous Gluconate | . 13 mg |
| Potassium Iodide | 15 mg |

Other ingredients: magnesium stearate, microcrystalline cellulose, silicone dioxide

INDICATIONS AND USAGE

Prenatal and Postnatal prescriptive Folic Acid

WARNINGS

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under age 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

PRECAUTIONS

Call your licensed medical practitioner about side effects.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1 tablet once or twice daily or as prescribed by a licensed practitioner.

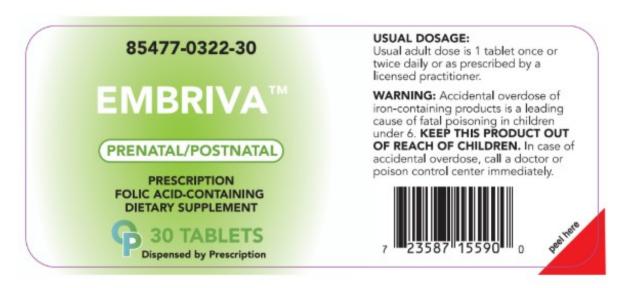
HOW SUPPLIED

Bottles of 30: 85477-0322-30

Storage

KEEP THIS AND ALL MEDICATION OUR OF THE REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL



EMBRIVA

ascorbic acid, cholecalciferol, thiamine, pyridoxal phosphate, folic acid, methylcobalamin, calcium carbonate, ferrous gluconate, potassium iodide tablet

| Product Information | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:85477-322 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|--------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| PYRIDOXAL PHOSPHATE ANHYDROUS (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII: F06SGE49M6) | PYRIDOXAL PHOS PHATE ANHYDROUS | 2.5 mg | |
| POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q) | POTASSIUM IODIDE | 0.15 mg | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 125 mg | |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - | CHOLECAL CIFEROL | 0.0125 | |

| UNII:1C6V77QF41) | CHOLECALCIFEROL | บ.บารว mg |
|---|-----------------|-----------|
| THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J) | THIAMINE | 1.4 mg |
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 1 mg |
| METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W) | METHYLCOBALAMIN | 1 mg |
| CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII: 2M83C4R6ZB) | CALCIUM CATION | 200 mg |
| FERROUS GLUCONATE (UNII: U1B11I423Z) (FERROUS CATION - UNII: GW89581OWR) | FERROUS CATION | 13 mg |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

| Product Characteristics | | | |
|-------------------------|------|--------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 19mm |
| Flavor | | Imprint Code | |
| Contains | | | |

| ı | Packaging | | | |
|---|------------------------|--|-------------------------|-----------------------|
| | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 NDC:85477- 322-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/08/2025 | |

| Marketing Information | | | |
|--------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 08/08/2025 | |
| | | | |

Labeler - Oncora Pharma, LLC (119482542)

Revised: 8/2025 Oncora Pharma, LLC