

FLORAFOL- multivitamin and fluoride supplement tablet
Pangea Pharmaceuticals, 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.

FloraFol

(Multivitamin with 0.5 mg of Fluoride) Chewable Tablet

Multivitamin and Fluoride Supplement

Multivitamin and Fluoride Supplement

Supplement Facts

Serving Size: 1 Tablet

Servings Per Container: 30

| Amount Per Serving | | % Daily Values | |
|---|-------------|-----------------------|--|
| | | %DV | %DV Children Children 4-8 9 years and years older |
| Vitamin A (as Retinyl Acetate) | 700 mcg | 175% | 117% |
| Vitamin B1 (as Thiamine Mononitrate) | 1 mg | 167% | 111% |
| Vitamin B2 (as Riboflavin) | 1 mg | 167% | 111% |
| Niacin (as Niacinamide) | 12 mg | 150% | 100% |
| Vitamin B6 (as Pyridoxine HCl) | 1 mg | 192% | 115% |
| Vitamin B12 (as Cyancobalamin) | 3.5 mcg | 292% | 194% |
| Folate (as L-Methylfolate, Calcium Salt Metafolin) | 250 mcg DFE | 125% | 83% |
| Vitamin C (as Sodium Ascorbate) | 70 mg | 280% | 156% |
| Vitamin D (as Cholecalciferol) | 12 mcg | 80% | 80% |
| Vitamin E (as D-Alpha-Tocopherol) | 11.5 mg | 164% | 105% |
| Fluoride (as Sodium Fluoride) | 0.5 mg | 50% | 25% |

Other Ingredients: Xylitol, Sorbitol, Citric Acid Anhydrous, Stevia/Monk Fruit, Berry Flavor, Beet Root Juice, Carrageenan, Magnesium Stearate, Stearic Acid

Allergens: Fish Oil

Caution: This product should be chewed and is not recommended for children under age 4 due to risk of choking.

Distributed by:
Pangea Pharmaceuticals, LLC
Brielle, NJ 08730

1-855-892-8224
www.florafolrx.com

PRINCIPAL DISPLAY PANEL - Multivitamin with 0.5 mg of Fluoride

81279-102-30

FloraFol

(Multivitamin with 0.5 mg of Fluoride) Chewable Tablet MULTIVITAMIN & FLUORIDE SUPPLEMENT BERRY FLAVOR

0.5 mg

30 Tablets



FLORAFOL

multivitamin and fluoride supplement tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:81279-102 |
| 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 | 700 ug |
| THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J) | THIAMINE | 1 mg |
| RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR) | RIBOFLAVIN | 1 mg |
| NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4) | NIACINAMIDE | 12 mg |
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z) | PYRIDOXINE | 1.15 mg |
| CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN | 3.5 ug |
| LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC) | LEVOMEFOLIC ACID | 250 ug |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 70 mg |

| | | |
|---|------------------------|---------|
| CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41) | CHOLECALCIFEROL | 12 ng |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9) | .ALPHA.-TOCOPHEROL, D- | 11.5 mg |
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| XYLITOL (UNII: VCQ006KQ1E) | |
| SORBITOL (UNII: 506T60A25R) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | pink | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:81279-102-30 | 1 in 1 PACKAGE | 06/10/2024 | |
| 1 | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 06/10/2024 | |

Labeler - Pangea Pharmaceuticals, LLC (117751012)

Registrant - Pangea Pharmaceuticals, LLC (117751012)