

To report a serious adverse event contact:
1-800-367-3395.

Manufactured by:
Nexgen Pharma, Inc.
Irvine, CA 92606

Distributed by:
Breckenridge Pharmaceutical, Inc.
Berlin, CT 06037

6802

Rev 06/19

51991-252-01
Folplex™ 2.2

Each Tablet Contains:
Folic Acid 2.2 mg
Vitamin B₆ 25 mg
Vitamin B₁₂ 500 mcg

Do not use this product if the inner safety seal under the cap is torn, broken or missing.

 **Medical Food**
100 Tablets

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

OTHER INGREDIENTS:
(peel back for complete listing)
See attached package insert for complete prescribing information.
Dispense in a tight, light-resistant container with a child-resistant closure, as defined in USP/NF. Protect from freezing.
Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). See USP Controlled Room Temperature. Protect from light and moisture.
Warning: Keep this and all medications out of the reach of children. In case of accidental overdose seek professional assistance or contact a poison control center immediately.

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Lift Here

7.9375"

Folplex™ 2.2

Each Orange Tablet Contains: 2.2 mg Folic Acid, 25 mg Vitamin B₆ and 500 mcg Vitamin B₁₂.

Other Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Crospovidone, Magnesium Stearate.

Coating: Hypromellose, Polydextrose, Titanium Dioxide, *FD&C Yellow No. 6 Aluminum Lake, Triacetin, Polyethylene Glycol 8000, Riboflavin.

*Contains FD&C Yellow No. 6 as a color additive.

Indications and Usage: For the dietary management for individuals with distinct nutritional needs of iron deficiencies. Folplex™ 2.2 is labeled as a medical food intended for use under the active and ongoing medical

supervision requiring medical care on a recurring basis for, among other things, instructions on the use of the medical food.

Medical Foods

Medical foods are intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of a normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does not require a prescription.

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

Precautions: Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

Adverse Reactions: Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

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

Warning: Keep this and all medications out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Dispense in a tight, light-resistant container with a child-resistant closure, as defined in USP/NF. Protect from freezing.

Storage: Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). See USP Controlled Room Temperature. Protect from light and moisture.

Dosage and Administration:

Adults - one tablet daily or as directed by a physician or health-care provider.

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continuing use.

How Supplied: Folplex™ 2.2 tablets are orange, oval-shaped tablets, debossed B 252. Supplied in bottles of 100, 51991-252-01.