

Calcium-Folic Acid Plus D Chewable Wafers

Rx Only

Description: Round-shaped, tan-colored chewable tablets. One side is bisected with “BP” above “706” and the other side is blank. Calcium-Folic Acid Plus D Chewable Wafers are a chewable Calcium and Folic Acid dietary supplement with Vitamin D, Magnesium and ingredients which are intended to supplement the dietary needs of individuals who could benefit from the vitamins, minerals and other dietary ingredients herein including, but not limited to, premenopausal, menopausal and postmenopausal women, as well as other individuals managing overall cardiovascular wellness through diet.

Supplement Facts

Serving Size: 1 wafer

	Amount Per Serving	% Daily Value
Vitamin D3 (as cholecalciferol)	7.5 mcg	40%
Vitamin B6 (as pyridoxine HCl)	10 mg	500%
Folic Acid (1000 mcg Folic Acid, USP)	1700 mcg DFE	430%
Vitamin B12 (as cyanocobalamin)	125 mcg	5210%
Calcium (as calcium carbonate)	500 mg	50%
Magnesium (as magnesium oxide)	50 mg	10%
Boron (as boron amino acid chelate)	250 mcg	**

** Daily value not established

Other Ingredients: Cocoa, Magnesium Stearate, Natural Milk Chocolate Flavor, Silicon Dioxide, Stearic Acid, Sucrose.

Indications and Usage: Calcium-Folic Acid Plus D Chewable Wafers are intended to supplement and help maintain healthy calcium, vitamin D, and folic acid levels in the diet which may help maintain healthy bones. Calcium and vitamin D supplementation may be useful in both preventing and treating osteoporosis. Vitamin D supplementation may be beneficial to those who are institutionalized and/or have reduced exposure to sunlight. Folic acid, vitamin B6, and vitamin B12 may help reduce the risk of cardiovascular disease by lowering blood levels of homocysteine. If dietary intake of calcium is inadequate, patients currently taking bisphosphonates for treatment of osteoporosis should be instructed to take calcium and vitamin D daily (Calcium-Folic Acid Plus D Chewable Wafers).

Contraindications: Calcium-Folic Acid Plus D Chewable Wafers are contraindicated in patients with hypersensitivity to any of its components. Calcium and vitamin D supplementation is contraindicated in those with hypercalcemia or conditions that may lead to hypercalcemia and in those who form calcium containing stones. Concomitant use of iron and calcium may inhibit the absorption of iron. Concomitant use of quinolones or tetracyclines with calcium may decrease the absorption of these medications. Folic acid is contraindicated in patients with untreated and uncomplicated pernicious anemia. It is also contraindicated in those with anaphylactic sensitivity to folic acid. The use of folic acid doses above 1 milligram/day may precipitate or exacerbate the neurological damage of vitamin B12 deficiency. High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs; carbamazepine, fosphenytoin, phenytoin, phenobarbital and valproic acid.

Precautions: Folic acid, especially in doses above 1.0 mg daily,

may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

Drug Interactions: As little as 5 mg of pyridoxine (vitamin B6) daily can decrease the efficacy of levodopa. Therefore, Calcium-Folic Acid Plus D Chewable Wafers are not recommended for patients undergoing such therapy.

Information for Patients: Calcium-Folic Acid Plus D Chewable Wafers are dietary supplements for use only under the direction and supervision of a licensed physician. Total intakes of greater than 2,000 mg of individual provide no added benefit to bone health.

Pregnancy: Shall only be administered under the supervision of a physician.

Pediatric: Not recommended for pediatric use.

Adverse Reactions: Adverse reactions have been reported with specific vitamins and minerals, but generally at levels substantially higher than those in Calcium-Folic Acid Plus D Chewable Wafers. However, allergic and/or idiosyncratic reactions to vitamins even at lower potencies or any ingredient are possible.

WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Dosage and Administration: Chew one wafer twice daily or as prescribed by a physician.

Storage: Keep tightly closed in a dry place. Store at 20° - 25°C (68 - 77°F); excursions permitted to 15° - 30°C (59° - 86°F). [See USP Controlled Room Temperature].

How Supplied: Calcium-Folic Acid Plus D Chewable Wafers are supplied in bottles of 60 wafers (42192-706-60). The listed product number is not a National Drug Code, but has merely been formatted to comply with industry practice standard for pharmacy and insurance computer systems.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the dietary ingredients, other ingredients and information provided herein.

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.

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005
1-800-541-4802
L-0243 Rev. 0320-01