

FORVIA[®] PRODUCT INFORMATION

FORVIA[®] Tablets and Chewables
(for' vee-uh)

OTC

High-Potency Multivitamin / Mineral Tablets and Chewables

DESCRIPTION: FORVIA[®] is a vitamin and mineral dietary supplement formulated as oral multinutrient tablets and chewable wafers intended to meet the special nutrient needs of people with gastrointestinal conditions such as

- Inflammatory Bowel Disease, including Crohn's disease and Ulcerative colitis
- Celiac disease
- Weight loss surgery
- Ostomy
- Bowel resection

FORVIA Tablets and Chewables are formulated to promote good absorption of their vitamins and nutrients and are specially formulated to avoid irritation of the gastrointestinal system and do not include artificial flavoring, lactose, gluten or magnesium.*

PROPERTIES: The adult dose of two tablets or chewable wafers daily has the following properties (see Composition listed below for detailed information on tablet and wafer composition):

- FORVIA contains the fat-soluble vitamins A, D, E and K in water-miscible forms to promote good absorption and utilization. Water-miscible forms more easily mix with body enzymes and bile salts to create absorbable particles called micelles. Vitamin D, important for maintaining bone mass, is supplemented at 2 times the Daily Value because is not optimally absorbed in IBD and absorption may be inhibited by steroids used in the treatment of IBD.
- FORVIA contains vitamin C and iron in the ratio and quantities shown to increase iron absorption when given together. Iron is provided as ferrous fumarate, which is highly soluble in the gastrointestinal tract, well tolerated orally and was less toxic than ferrous sulfate or ferrous gluconate in laboratory studies.
- FORVIA contains folic acid, the daily administration of which has been found in a number of studies to be associated with a reduced risk for the development of colorectal cancer or dysplasia in individuals with ulcerative colitis.
- FORVIA contains 1000 mcg of vitamin B₁₂ (cyanocobalamin). B₁₂ may be poorly absorbed in patients with IBD, particularly in extensive Crohn's disease, because B₁₂ in diet is absorbed by an active transport mechanism in the terminal ileum (lower part of small intestine). A small percentage of a large oral dose such as in FORVIA Tablets can be absorbed passively throughout the small intestine and maintain B₁₂ levels in IBD patients. Patient B₁₂ status should be monitored when switching from parenteral B₁₂ injections to FORVIA Tablets.
- FORVIA contains zinc, important for wound healing and immune function, which is supplemented at 150% of the Daily Value because zinc may be lost through increased excretion in individuals with IBD.
- FORVIA contains dicalcium phosphate, a "non-gassy"/non-carbonate form of calcium.
- FORVIA is lactose-free and contains no sugars (except fructose in the Chewables), dyes, artificial sweeteners or flavorings.
- FORVIA contains no gluten and may be suitable for patients with Celiac Disease.*

*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.

SUPPLEMENT FACTS

Serving Size 2 Tablets or Chewables

	Amount Per Serving	% DV*
Vitamin A (as retinylacetate)	5,000 IU	100%
Vitamin C	200 mg	330%
Vitamin D (as cholecalciferol)	800 IU	200%
Vitamin E (as dl-alpha-tocopherol acetate)	150 IU	500%
Vitamin K (phytonadione)	80 mcg	100%
Thiamin (Vitamin B ₁)	10 mg	670%
Riboflavin (Vitamin B ₂)	10 mg	590%
Niacin (as niacinamide)	20 mg	100%
Vitamin B ₆ (as pyridoxine HCL)	10 mg	500%
Folic Acid	0.4 mg	100%
Vitamin B ₁₂ (as cyanocobalamin)	1,000 mcg	16,670%
Biotin	0.3 mg	100%
Pantothenic acid (as calcium d-pantothenate)	10 mg	100%
Calcium (as dicalcium phosphate)	200 mg	20%
Iron (as ferrous fumarate)	30 mg	170%
Iodine (as potassium iodide)	150 mcg	100%
Zinc (as zinc oxide)	22.5 mg	150%
Selenium (as selenium yeast)	70 mcg	100%
Copper (as cupric oxide)	2.0 mg	100%
Manganese (as manganese sulfate)	2.0 mg	100%

*Percent Daily Values based on a 2,000 calorie diet

Other INGREDIENTS:

Tablets - calcium stearate, calcium silicate, silicon dioxide, crospovidone, zinc stearate, croscarmellose sodium, hydroxypropyl methylcellulose, titanium dioxide, microcrystalline cellulose, stearic acid.

Chewables –dextrates, fructose, vegetable stearine, natural orange flavor, silicon dioxide, magnesium stearate.

RECOMMENDATIONS: FORVIA tablets and Chewables are recommended for use under medical supervision in individuals who do not obtain sufficient quantities of certain of the essential vitamins and minerals from diet, especially due to poor absorption or increased excretion of nutrients, or dietary restrictions associated with gastrointestinal conditions such as inflammatory bowel disease (IBD) (ulcerative colitis; Crohn's disease), celiac disease and bariatric or other surgeries.

DOSAGE: Adults: Two tablets daily in a single or divided dose, or as directed by physician
Children under age 12: As directed by physician

PRECAUTIONS: Do not exceed recommended dosage. FORVIA is not intended for the treatment of pernicious anemia, and the treatment of any anemic conditions should be under the advice and supervision of a physician. Intake of folic acid from all sources should be limited to 1.0 mg/day or less to prevent the masking of vitamin B₁₂ deficiencies. Vitamin K interferes with the action of anticoagulant drugs. Individuals taking anticoagulants should consult their physician before taking FORVIA. Excessive quantities of vitamin A may be hazardous to the embryo or fetus when taken during pregnancy. Women of childbearing potential should consult their physician concerning their total daily vitamin A intake. Because oral iron products interfere with oral absorption of tetracycline antibiotics, these products should not be taken within two hours of each other. Serious deficiencies of individual vitamins or minerals require medical evaluation and may require treatment and monitoring. *Dermatitis herpetiformis* is a rare hereditary skin disease linked to celiac disease. *Dermatitis herpetiformis* patients should not consume FORVIA® or other iodine-containing supplements or foods high in iodine while rash is present

WARNINGS: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

ADVERSE REACTIONS: FORVIA Tablets are generally well-tolerated. There have been occasional reports of stomach distress or diarrhea. Individuals who are particularly sensitive to vitamin and mineral formulations may wish to divide the daily dose and take one tablet in the morning and one in the afternoon or evening with a meal or snack. There have been two reports of discolored stools, possibly due to iron in the formulation.

HOW SUPPLIED: Ivory capsule-shaped tablets imprinted FORVIA in bottles of 60 and 180 tablets with child-resistant safety cap. Off white natural orange flavor chewable wafers imprinted FORVIA 05 in round bottles of 60. Do not use if safety seal under cap is broken or missing.

STORAGE: Store at controlled room temperature, 59° - 86°F (15° - 30°C)

MANUFACTURED FOR:

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