

# FORVIA® LABELING

## (Package Insert)

**FORVIA™ Tablets**  
(for' vee-uh)

**OTC**

### High-Potency Multivitamin / Mineral Tablets

**DESCRIPTION:** FORVIA™ is an oral multivitamin tablet formulated to meet the special nutrient needs of individuals who do not obtain sufficient quantities of certain essential vitamins and minerals from diet, especially because of poor absorption or increased excretion of nutrients or dietary restrictions due to gastrointestinal conditions such as inflammatory bowel disease (IBD).

#### **PROPERTIES:**

- FORVIA contains the fat-soluble vitamins A, D, E and K in water-miscible forms to enable good absorption and utilization. Vitamin D, important for maintaining bone mass, is supplemented at 2 times the Daily Value, since it is not optimally absorbed in IBD and 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 B<sub>12</sub> (cyanocobalamin). B<sub>12</sub> may be poorly absorbed in patients with IBD, particularly in extensive Crohn's disease.
- 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 calcium diphosphate, a "non-gassy"/non-carbonate form of calcium.
- FORVIA contains no magnesium in the active or other ingredients because magnesium is a cathartic.
- FORVIA is lactose-free and contains no sugars, dyes, artificial sweeteners or flavorings.

**COMPOSITION:**

<u>Vitamins</u>	<u>One Tablet</u>	<u>2 Tablets Provide</u>	
	<u>(Amount)</u>	<u>(Amount)</u>	<u>% of Daily Value</u>
Vitamin A	2,500 IU	5,000 IU	100
Vitamin D	400 IU	800 IU	200
Vitamin E	75 IU	150 IU	500
Vitamin K	40 mcg	80 mcg	100
Vitamin C	100 mg	200 mg	330
Vitamin B <sub>1</sub>	5 mg	10 mg	670
Vitamin B <sub>2</sub>	5 mg	10 mg	590
Vitamin B <sub>6</sub>	5 mg	10 mg	500
Vitamin B <sub>12</sub>	500 mcg	1,000 mcg	16,670
Folic Acid	0.2 mg	0.4 mg	100
Niacin	10 mg	20 mg	100
Biotin	0.15 mg	0.3 mg	100
Pantothenic acid	5 mg	10 mg	100
 <u>Minerals</u>			
Iron (elemental)	15 mg	30 mg	170
Calcium (elemental)	100 mg	200 mg	20
Zinc	11.25 mg	22.5 mg	150
Selenium	35 mcg	70 mcg	100
Copper	1.0 mg	2.0 mg	100
Iodine	75 mcg	150 mcg	100
Manganese	1.0 mg	2.0 mg	100

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

**INGREDIENTS:** Vitamin A acetate, cholecalciferol, dl-alpha tocopherol acetate, phytonadione, ascorbic acid, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, folic acid, niacinamide, biotin, D-calcium pantothenate, ferrous fumarate, dicalcium phosphate, zinc oxide, selenium yeast, cupric oxide, potassium iodide, manganese sulfate, calcium stearate, calcium silicate, silicon dioxide, crospovidone, zinc stearate, croscarmellose sodium, hydroxypropyl methylcellulose, titanium dioxide, microcrystalline cellulose, stearic acid.

**INDICATIONS:** FORVIA tablets are indicated 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).

**DOSAGE:** Adults: Two tablets daily in a single or divided dose  
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 B<sub>12</sub> 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.

**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.

**HOW SUPPLIED:** Pale yellow capsule-shaped tablets imprinted FORVIA in bottles of 60 with child-resistant safety cap. Do not use if imprinted seal under cap is broken or missing.

**UPC** \_\_\_\_\_ Bottle of 60 Tablets

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

**MANUFACTURED FOR:**

INOVERA Bioscience Development, LLC  
921 Bethlehem Pike  
P.O. Box 790  
Spring House, PA 19477 USA

# LABEL

## FORVIA™

Multivitamin / Mineral

**60 Tablets**

**Recommended Dosage:**

Adults: 2 tablets daily  
 Children under age 12: as  
 Directed by physician

**Bar  
Code**

**Company  
Logo**

Do not use if imprinted seal under cap is broken or missing

**COMPOSITION:**

<u>Vitamins</u>	<u>One Tablet</u>		<u>% of Daily Value*</u>
	<u>Contains</u> <u>(Amount)</u>	<u>2 Tablets Provide</u> <u>(Amount)</u>	
Vitamin A (retinylacetate)	2,500 IU	5,000 IU	100
Vitamin D (cholecalciferol)	400 IU	800 IU	200
Vitamin E (dl-alpha tocopherol acetate)	75 IU	150 IU	500
Vitamin K (phytonadione)	40 mcg	80 mcg	100
Vitamin C (ascorbic acid)	100 mg	200 mg	330
Vitamin B <sub>1</sub> (thiamine mononitrate)	5 mg	10 mg	670
Vitamin B <sub>2</sub> (riboflavin)	5 mg	10 mg	590
Vitamin B <sub>6</sub> (pyridoxine hydrochloride)	5 mg	10 mg	500
Vitamin B <sub>12</sub> (cyanocobalamin)	500 mcg	1,000 mcg	16,670
Folic Acid	0.2 mg	0.4 mg	100
Niacin (niacinamide)	10 mg	20 mg	100
Biotin	0.15 mg	0.3 mg	100
Pantothenic acid	5 mg	10 mg	100
<u>Minerals</u>			
Iron (elemental)	15 mg	30 mg	170
Calcium (elemental)	100 mg	200 mg	20
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Copper	1.0 mg	2.0 mg	100
Iodine	75 mcg	150 mcg	100
Manganese	1.0 mg	2.0 mg	100

\*Daily values are based on a 2,000 calorie diet

**For use under medical supervision**

**OTHER INGREDIENTS:** Crospovidone, microcrystalline cellulose, stearic acid, zinc stearate, calcium stearate, calcium silicate, croscarmellose sodium, silicon dioxide, hydroxypropyl methylcellulose, titanium dioxide.

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