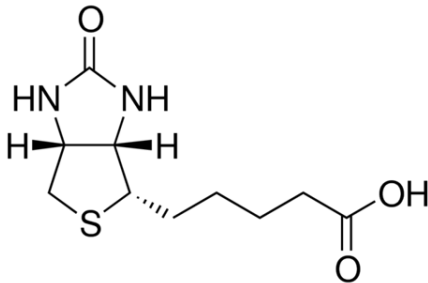


Biotin 5,000 mcg

TECHNICAL SUMMARY

Biotin is a water-soluble vitamin necessary for cell growth, the production of fatty acids, and the metabolism of fats and amino acids.* It also plays key roles in gluconeogenesis and fatty acid synthesis, and is therefore critical for maintaining proper glucose and lipid metabolism.* Biotin is also known to be important for healthy skin, hair and nails.*

Structure formula:



Chemical name:

Biotin, also known as coenzyme R, vitamin H or Vitamin B₇
Systemic name: 5-[(3aS,4S,6aR)-2-oxohexahydro-1H-thieno [3,4-d]imidazol-4-yl] pentanoic acid.

Allergen and Additive Disclosure: Not manufactured with wheat, gluten, soy, milk, egg, fish, shellfish, tree nut or sesame ingredients. Produced in a GMP facility that processes other ingredients containing these allergens.

Delivery Form: Vegetarian Capsules

ROLE AS NUTRIENT/FUNCTION

Biotin is a water-soluble B vitamin that plays an important role in many enzymatic activities.* It acts as an enzymatic co-factor to carboxylases involved in fatty acid oxidation and synthesis, amino acid metabolism, and glucose metabolism.* It also reacts with propionyl-CoA carboxylase as an essential step for the metabolism of isoleucine, valine, methionine, and threonine.* With beta-methyl-crotonyl-CoA carboxylase biotin helps to metabolize leucine.*

Biotin also plays key roles in histone modifications, gene regulation (by modifying the activity of transcription factors), and cell signaling.*

NATUROKINETICS®

Liberation: Disintegration of the vegetable capsule is measured in water using a USP testing method with disintegration between zero to 60 minutes.

Absorption: After oral administration, biotin is rapidly and extensively absorbed in the intestine via active and passive diffusion. This has been demonstrated in pharmacokinetic studies indicating that biotin is highly bioavailable. (Figure 1) In a study commissioned by Protocol For Life Balance®, peak serum concentrations for biotin were achieved within 2-4 hours of oral administration of 5,000 mcg biotin. (Figure 2)

Distribution: Free biotin accumulates in the liver (principal site of biotin utilization), kidney, cerebral capillaries, and peripheral blood mononuclear cells. Most biotin in plasma is free, however, small amounts are reversibly

Supplement Facts

Serving Size 1 Veg Capsule

| | Amount Per Serving | % Daily Value |
|--------|--------------------|---------------|
| Biotin | 5 mg (5,000 mcg) | 16,667% |

Other ingredients: Rice Flour, Hypromellose (cellulose capsule), Stearic Acid (vegetable source) and Silicon Dioxide.

- Normal Glucose Metabolism*
- Healthy Hair, Skin & Nails*

SUGGESTED USAGE: Take 1 capsule daily, or as directed by your healthcare practitioner.

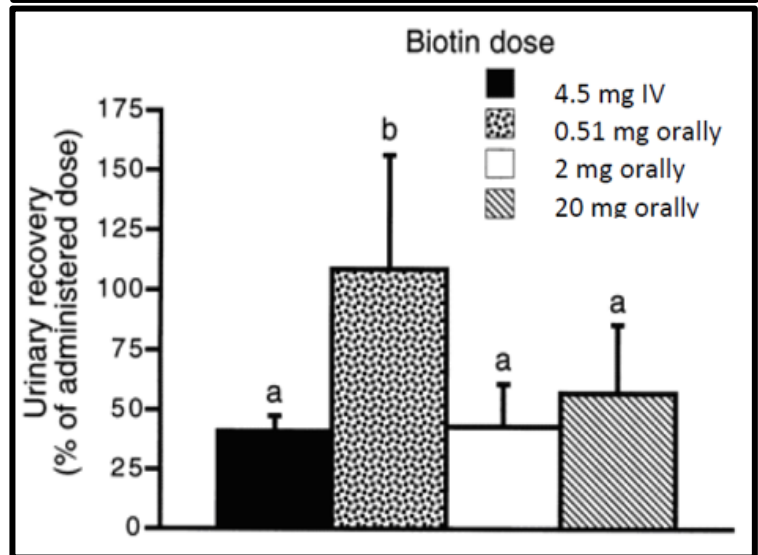


Fig. 1. Mean (±SD) urinary recovery of biotin plus metabolites within 24 h of biotin administration to 6 adults. Columns with different letters are significantly different, P < 0.05.

bound and covalently bound to plasma protein (approximately 7 and 12%, respectively); binding to human serum albumin likely accounts for the reversible binding. Biotinidase has been proposed as a biotin binding protein or biotin carrier protein for the transport into cells. Biotin is transported across the blood-brain barrier.

Metabolism: Once biotin is absorbed into the cell, it is metabolized through beta-oxidation. Cleavage of the carbon units leads to the formation of bisnorbiotin, tetranorbiotin, and other related metabolites. Spontaneous (non-enzymatic) decarboxylation of beta-keto acids (beta-keto-biotin and beta-keto-bisnorbiotin) leads to formation of bisnorbiotin methylketone and tetranorbiotin methylketone; these catabolites appear in urine. In the cytoplasm, the sulfur in the heterocyclic portion of biotin undergoes sulfur oxidation, particularly in the smooth endoplasmic

reticulum, which leads to the formation of biotin sulfoxide and biotin sulfone.

Elimination: While an active reabsorption system exists in kidneys, biotin and its metabolites are ultimately excreted through the urine.



Fig. 2. Average serum biotin levels before, 2, 4 and 24 hours following a single administration of one capsule of Biotin 5,000 mcg (Protocol For Life Balance®, Bloomingdale, IL; Product # P0471) in healthy adult volunteers.

Approximately half of the urinary excretion consists of unmetabolized biotin and the other half is composed of biotin metabolites, mostly, bisnorbiotin, bisnorbiotin methylketone, biotin-*d,l*-sulfoxide, and biotin sulfone.

CLINICAL VALIDATION

- In a small open label clinical study where women with brittle nails receiving 2.5 mg/d biotin for up to 15 months, authors observed a significant 25% increase in nail thickness from 256 μm to 319 μm ($p < 0.05$, as measured using scanning electron microscopy).^{*} Other objective nail structure improvements observed in some of the volunteers were a reduction in lamellar splitting of nails, a reduction in the irregularity and multidirectional orientation of the dorsal nail cells.^{*} The average time until a favorable effect of biotin supplementation is 5.5 \pm 2.3 months.^{*}

SAFETY INFORMATION

Tolerability: Biotin is safe and well tolerated for adults and infants. Daily doses up to 200 mg orally have been given to treat biotin-responsive inborn errors of metabolism and acquired biotin deficiency. Toxicity has not been reported.

Contraindications: None known.

INTERACTIONS

Drug Interactions: None known.

Supplement Interactions: Theoretically, biotin absorption may be affected when taken with alpha-lipoic acid or vitamin B₅ due to these molecules share the sodium-dependent transporter. Taking biotin (10 mg/d) with pantothenic acid (300 mg) may cause eosinophilic pleuropericardial effusion.

Interaction with Lab Tests: Biotin-based immunoassays (using biotin-streptavidin technology) are typically used for the evaluation of endocrine function, as well as for other tests such as troponin, serum folate, vitamin D, hepatitis A & B antibodies, and others. Some of these tests are at risk of producing falsely decreased or increased results when biotin is present in the tested sample. Depending on the test method, biotin concentrations in biological samples as low as 8.6 ng/mL could trigger a difference greater than $\pm 10\%$ in test results.

STORAGE

Store in a cool, dry place in original sealed container.