

**Vitafo<sup>l</sup>-Nano**  
**Preconception and Prenatal Supplement**  
**Rx**

**COMPOSITION:**

Amount per Tablet:

**VITAMINS AND MINERALS:**

Vitamin D (as cholecalciferol)	1000 IU
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate	1 mg
(as Folic acid USP 0.4 mg and L-methylfolate calcium 0.6 mg, as Metafolin® CAS# 151533-22-1)	
Vitamin B12 (as cyanocobalamin)	12 mcg
Iron (as ferrous fumarate)	18 mg
Iodine (as potassium iodide)	150 mcg

**Other Ingredients:**

Microcrystalline cellulose, hydroxypropylcellulose, modified food starch, croscarmellose sodium, magnesium stearate, sucrose, silicon dioxide, dibasic calcium phosphate, polyvinyl alcohol, titanium dioxide (as color), polyethylene glycol, talc, sodium ascorbate, medium chain triglycerides, dl-alpha-tocopherol, sucralose, FD&C Blue #2 Aluminum Lake.

**USAGE:** Vitafo<sup>l</sup>-Nano provides vitamin and mineral supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.

**CONTRAINDICATIONS:** Vitafo<sup>l</sup>-Nano is contraindicated in patients with hypersensitivity to any of its components or color additives.

Folic acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid.

Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (vitamin B12).

**WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or a Poison Control Center immediately,**

**WARNINGS/PRECAUTIONS:** Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur.

Prolonged use of iron salts may produce iron storage disease.

Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission

may occur while neurological manifestations remain progressive.

The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency.

Avoid Overdosage. Keep out of the reach of children.

**DRUG INTERACTIONS:** High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs; carbamazepine, fosphenytoin, phenytoin, phenobarbital, valproic acid. Folic acid may decrease a patient's response to methotrexate.

Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones.

Consult appropriate references for additional specific vitamin-drug interactions.

**Information for Patients:** Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breastfeeding.

**Pediatric Use:** Not for pediatric use.

**ADVERSE REACTIONS:** Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in Vitafo<sup>l</sup>-Nano. However, allergic and idiosyncratic reactions are possible at any dose. Reported adverse events include skin ailments, gastrointestinal complaints, glucose abnormalities, and visual problems.

**DIRECTIONS FOR USE:** Before, during and after pregnancy, one tablet daily, or as directed by a physician.

**HOW SUPPLIED:** Vitafo<sup>l</sup>-Nano is available as a light blue, round tablet imprinted with "94" on one side. Available in Box of Unit-Dose pack of 30 (2 child resistant blister cards of 15 tablets), 0642-0094-30 and as professional samples, 0642-0094-03.

Store at Controlled room temperature at 20°-25°C (68°-77°F). Avoid excessive heat, light, moisture and humidity.

Rx

**Distributed by:**  
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