

INTAFOL-D

COMPOSITION: Each tablet contains: L-Methyl Folate 1.0 mg, Methylcobalamin 1500 mcg, Pyridoxal-5-Phosphate 0.5 mg, (DHA) 40% 200 mg, Vitamin D3 2000 IU. Excipients q.s

THERAPEUTIC INDICATIONS: As a dietary supplement in second and third trimester of pregnancy and during lactation.

DOSAGE AND ADMINISTRATION: One tablet daily during pregnancy or as directed by physician.

CONTRAINDICATIONS: Hypersensitivity to any of the ingredient in the product. Hypervitaminosis D. Nephrolithiasis. Diseases or conditions resulting in hypercalcaemia and/or hypercalciuria. Severe renal impairment.

WARNINGS AND PRECAUTIONS: Intafol-D should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. Intafol D should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of vitamin D to its active form. These patients should be monitored with regard to the calcium content in serum and urine. Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including increased bleeding time and reduced clotting ratio (INR). Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

Pediatric Use: Not recommended for paediatric patients

DRUG INTERACTIONS:

Vitamin D3: Concomitant treatment with phenytoin or barbiturates, glucocorticoids can decrease the effect of vitamin D. Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.

L methyl folate : Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, phenobarbital and lamotrigine have been shown to impair folate absorption and increase the metabolism of circulating folate. Additionally, concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the level of this AED in the blood and allowing breakthrough seizures to occur.

Methotrexate, alcohol (in excess), sulfasalazine, cholestyramine, colchicine, colestipol, L-dopa, methylprednisone, NSAIDs (high dose), pancreatic enzymes, pentamidine, pyrimethamine, smoking, triamterene, and trimethoprim may decrease folate plasma levels.

Methylcobalamin: Antibiotics, cholestyramine, colchicine, colestipol, metformin, para-aminosalicylic acid, and potassium chloride may decrease the absorption of vitamin B12. Nitrous oxide can produce a functional vitamin B12 deficiency.

Pyridoxal 5 phosphate: Action of levodopa is antagonized by vitamin B6.

DHA: No significant drug interactions.

ADVERSE REACTIONS: All ingredients are well tolerated. Uncommon adverse effects can be hypercalcaemia and hypercalciuria. Rare adverse can include pruritus, rash and urticaria.

OVERDOSE: The most serious consequence of acute or chronic overdose is hypercalcaemia due to vitamin D toxicity. Symptoms may include nausea, vomiting, polyuria, anorexia, weakness, apathy, thirst and constipation. Treatment should consist of stopping all intake of Intafol D and rehydration. (For details, please refer full prescribing information)

(For the use of a registered medical practitioner or hospital or laboratory only)