**NUTROLIN-B PLUS Capsules (Lactic acid bacillus + Vitamin B)**

### Composition

**NUTROLIN-B PLUS Capsules**
Each capsule contains:
- Lactic Acid Bacillus .....40-10^6 spores
- Pyridoxine Hydrochloride ...1 mg
- Nicotinamide ..................25 mg
- Cyanocobalamin ................7.5 mcg
- Folic Acid ...................750 mcg

### Dosage Form

Capsule for oral use

### Description

**NUTROLIN-B PLUS Capsules** are a combination of multivitamins with lactic acid bacillus.

### Pharmacology

#### Pharmacodynamics

Despite the transient nature of this organism in the digestive tract, the changes that lactic acid bacillus produces causes a shift in the environment in support of a complex gastrointestinal flora. The mechanism of action is presumed to be a result of improving gastrointestinal ecology made possible by replenishing the quantity of desirable obligate microorganisms and antagonizing pathogenic microbes. Two isomeric forms of lactic acid can be produced by lactic acid-producing bacteria dextrorotatory (D(-)) lactic acid and levorotatory (L(+)) lactic acid. L(+) lactic acid is completely metabolized in the body; however, D(-) lactic acid is not completely metabolized, resulting in a degree of metabolic acidosis. *Lactobacillus sporogenes* produces only L(+) lactic acid. *L. sporogenes* assumed to produce bacteriocins and short-chain fatty acids. As the organism grows, it assimilates and incorporates cholesterol into its cellular structure. *L. sporogenes* possesses significant beta-galactosidase (lactase) activity in *vitro*.

Vitamin B₆ has anti-neurotoxic activity and may have activity in a number of inborn errors of
metabolism, including pyridoxine-dependent seizures in infants, sideroblastic anaemia, primary hyperoxaluria, homocystinuria, and cystathioninuria. Vitamin B₆ has putative anti-atherogenic, immunomodulatory, anticarcinogenic and mood modulatory activities. Nicotinamide may have anti-diabetogenic activity in some individuals. It may also have antioxidant, anti-inflammatory and anticarcinogenic activities. Nicotinamide has putative activity against osteoarthritis and granuloma annulare.

Pharmacokinetics

Subsequent to oral administration, L. sporogenes passes through the stomach in its spore form and upon arrival in the duodenum, germinates and multiplies rapidly. Estimates suggest that the average duration of time between oral dosing and germination is 4 hours. After germination, L. sporogenes is metabolically active in the intestines, producing lactic acid. L sporogenes is considered semi-resident, indicating that it takes up only a temporary residence in the human intestines. Spores of L. sporogenes are excreted slowly via the faeces for approximately 7 days after discontinuation of administration.

Pyridoxine hydrochloride is the principal form of vitamin B₆ used for food fortification and in nutritional supplements. Pyridoxal 5'-phosphate is also available as a nutritional supplement. The phosphorylated forms of vitamin B₆ undergo hydrolysis in the small intestine via alkaline phosphatase, and the non phosphorylated forms of the vitamin are absorbed by a non-saturable passive diffusion process, mainly in the jejunum. Most of the absorbed vitamin B₆ is transported via the portal circulation to the liver. In the liver, pyridoxine, pyridoxal and pyridoxamine are metabolized to pyridoxine 5'-phosphate, pyridoxal 5'-phosphate and pyridoxamine 5'-phosphate by pyridoxal 5'-phosphate kinase. Pyridoxal 5'-phosphate is secreted by the liver and transported by the systemic circulation to the various tissues of the body. Pyridoxal 5'-phosphate is the primary form of vitamin B₆ in the circulation and is bound to serum albumin. The principal catabolite of vitamin B₆ is 4-pyridoxic acid, which is the primary form of the vitamin excreted in the urine. 4-Pyridoxic acid, which is principally formed in the liver, accounts for approximately 50% of the vitamin B₆ compounds in the urine. At very high doses of vitamin B₆, which is mainly in the form of pyridoxine, much of the dose is excreted unchanged in the urine.

Nicotinamide is efficiently absorbed from the gastrointestinal tract. Doses of up to 3 to 4 grams of nicotinamide are almost completely absorbed. Nicotinamide is transported via the portal circulation to the liver and via the systemic circulation to the various tissues of the body. Nicotinamide enters most cells by passive diffusion and enters erythrocytes by facilitated transport.

Nicotinamide is metabolized to NAD++, which, in turn, has a number of metabolic opportunities, including the formation of nicotinamide, NADP++ (nicotinamide adenine dinucleotide phosphate), NAD (nicotinamide 5'-mononucleotide), cyclic ADP-ribose and NAADP (nicotinic acid dinucleotide phosphate). NAD++ also serves as the substrate for mono(ADP-ribosyl)ation and poly(ADP-ribosyl)ation. Poly(ADP-ribosyl)ation is catalysed by PARP. Nicotinamide may be converted to nicotinic acid via the enzyme nicotinamidase. In the liver, the principal catabolic products of high-dose nicotinamide are N'-methylnicotinamide, N'-methyl-5-carboxamide-2-pyridone, N'-methyl-5-carboxamide-4-pyridone and nicotinamide-N-oxide. High-dose nicotinamide is excreted in the urine as unchanged nicotinamide, N'-methylnicotinamide, N'-methyl-5-carboxamide-2-pyridone, N'-methyl-5-carboxamide-4-pyridone and nicotinamide-N-oxide.
### Indications

During and following antibiotic therapy, infantile diarrhoea, non-specific diarrhoea, for correction of disturbed gastrointestinal function in flatulence, malabsorption, to restore and stabilize defective intestinal flora, in aphthous stomatitis, fever blisters and canker sores, hepatic encephalopathy, adolescent acne, and vitamin B complex deficiency.

### Dosage And Administration

One capsule once daily.

### Contraindications

It is contraindicated in those hypersensitive to any component of this product, or a product containing the same ingredients.

High-dose nicotinamide (doses greater than 500 milligrams/day) is contraindicated in those with liver disease and in those with active peptic ulcer disease.

### Warnings And Precautions

#### General

The use of this product for any medical indication must be medically supervised.

Those who are being treated with levodopa without concurrently taking the levodopa decarboxylase inhibitor, carbidopa, should avoid doses of vitamin B6 of 5 milligrams or greater daily.

The use of vitamin B6 for the treatment of vitamin B6 deficiency, for the prophylaxis of isoniazid-induced peripheral neuropathy, for the treatment of vitamin B6 dependence disorders or for the treatment of any other medical condition requires medical supervision.

The use of nicotinamide for any medical indication requires medical supervision.

Those with a history of peptic ulcer disease, gastritis, liver disease, gallbladder disease, diabetes and gout should exercise caution in the use of high-dose nicotinamide.

Pregnant women and nursing mothers should avoid supplemental doses greater than the US RDA, unless higher doses are prescribed by their physicians.

### Drug Interactions

**Carbamazepine**

Concomitant use of nicotinamide and carbamazepine may decrease carbamazepine clearance. Chronic use of carbamazepine may result in a significant decrease in plasma pyridoxal 5'-phosphate levels.
Amiodarone
Concomitant use of vitamin B₆ and amiodarone may enhance amiodarone-induced photosensitivity reactions. Doses of vitamin B₆ greater than 5 to 10 milligrams/day should be avoided by those taking amiodarone.

Cycloserine
Cycloserine may react with pyridoxal 5’-phosphate to form a metabolically inactive oxime, which may result in a functional vitamin B₆ deficiency.

Ethionamide
The use of ethionamide may increase vitamin B₆ requirements.

Fosphenytoin
High doses of vitamin B₆ may lower plasma levels of phenytoin. Fosphenytoin is a prodrug of phenytoin.

Hydralazine
The use of hydralazine may increase vitamin B₆ requirements.

Isoniazid (isonicotinic acid)
Isoniazid reacts with pyridoxal 5’-phosphate to form a metabolically inactive hydrazone, which may result in functional vitamin B₆ deficiency.

Levodopa
Concomitant use of levodopa and vitamin B₆ in doses of 5 milligrams or more daily may reverse the therapeutic effects of levodopa. Vitamin B₆ does not reverse the therapeutic effects of levodopa if levodopa is taken concurrently with the levodopa decarboxylase inhibitor, carbidopa. Levodopa is typically administered as a combination product with carbidopa.

Penicillamine
Penicillamine may react with pyridoxal 5’-phosphate to form a metabolically inactive thiazolidine, which may result in a functional vitamin B₆ deficiency.

Phenelzine
Phenelzine may react with pyridoxal 5’-phosphate to yield a metabolically inactive hydrazone compound.

Phenobarbital
High doses of vitamin B₆ may lower plasma levels of phenobarbital.

Phenytoin
High doses of vitamin B₆ may lower plasma levels of phenytoin.

Theophylline
Theophylline may react with pyridoxal 5’-phosphate, leading to low plasma levels of the coenzyme. This may increase the risk of theophylline- induced seizures.

Valproic Acid
Chronic use of valproic acid may result in a significant decrease in plasma pyridoxal 5’-phosphate levels.

Alcoholic Beverages
Alcohol may increase the catabolism of pyridoxal 5’-phosphate. Chronic and excessive use of
alcoholic beverages can result in vitamin B₆ deficiency.

### Pregnancy

Pregnant women and nursing mothers should avoid supplemental doses greater than the US RDA, unless higher doses are prescribed by their physicians.

### Lactation

Pregnant women and nursing mothers should avoid supplemental doses greater than the US RDA, unless higher doses are prescribed by their physicians.

### Undesirable Effects

Probiotics are, generally, well tolerated. The most common adverse reactions with the use of probiotics are gastrointestinal and include flatulence and constipation.

Four cases of *Saccharomyces boulardii* fungaemia have been reported. All of the patients had indwelling catheters, and the fungaemia was thought to be due to catheter contamination.

There have been a few reports of *Lactobacillus* bacteraemia and endocarditis. In all the cases, there were underlying conditions, including cancer, diabetes mellitus and recent surgery. There was one death reported secondary to *Lactobacillus* bacteraemia.

There was one report of meningitis caused by *Bifidobacterium* in an infant.

Doses of vitamin B₆, typically in the form of pyridoxine, of up to 200 milligrams daily are generally well tolerated. One report showed severe sensory neuropathy in seven adults after pyridoxine intakes that started at 50 to 100 milligrams/day and were steadily increased to 2 to 6 grams/day over 2 to 40 months. None of the subjects in the report showed sensory neuropathy at doses of pyridoxine of less than 2 grams/day. There was one report of a woman who had been taking 200 milligrams/day of pyridoxine for 2 years without showing sensory neuropathy, who developed sensory neuropathy after she increased her pyridoxine dose to 500 milligrams/day. There are rare reports of sensory neuropathy occurring at pyridoxine doses in the range of 100 to 200 milligrams/day. The Food and Nutrition Board of the Institute of Medicine of the US National Academy of Sciences has concluded that the reports and studies showing sensory neuropathy at doses of pyridoxine less than 200 milligrams/day are weak and inconsistent, with the weight of evidence indicating that sensory neuropathy is unlikely to occur in adults taking pyridoxine at doses less than 500 milligrams/day.

Other adverse reactions reported with high doses of pyridoxine include nausea, vomiting, abdominal pain and loss of appetite, and breast soreness. Rare cases of pyridoxine-induced photosensitivity have been reported.

In contrast to nicotinic acid, nicotinamide does not cause flushing and has only very rarely been associated with diabetogenic effects. There are rare reports of elevations in liver tests and liver damage, including jaundice and parenchymal liver cell injury. These reports were in those using very high doses of Nicotinamide (10 grams or greater daily). Adverse reactions in those using high-dose nicotinamide, include nausea, vomiting, diarrhea, headache and dizziness.
Overdosage

None known.

Storage And Handling Instructions

Store in a cool, dry place.

Packaging Information

NUTROLIN-B PLUS: Strip of 15 capsules

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NUTROLIN-B PLUS Capsules

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