

Polybion® Forte Injection (Vitamin B-Complex)

پولی بیان® فورٹ انجکشن
(وٹامن بی کمپلیکس)

1. Composition:

Polybion® Forte Injection: Each 2ml contains:

Vitamin B ₁ (Thiamine Hydrochloride), USP.....	10 mg
Riboflavin 5'- Phosphate Sodium, USP.....	4 mg
Vitamin B ₆ (Pyridoxine Hydrochloride), USP.....	4 mg
Vitamin B ₁₂ (Cyanocobalamin), USP.....	8 mcg
Nicotinamide, USP.....	40 mg
Dexpanthenol, USP.....	6 mg

2. DESCRIPTION

Polybion® Forte I/M, I/V Ampoule is a combination of Vitamin B1, B2, B3, B5, B6 and B12.

3. THERAPEUTIC INDICATIONS

- To promote the recovery of severe mental and physical exhaustion
- In low weight to increase appetite, and for better utilization of nutrients
- Increased vitamin requirement, in old age and in growing age and in infectious disease.
- For rapid control of chronic and nutritional lesions.
- Promotes the absorption and increased functional efficacy of effected organ.
- To augment glucose therapy (improve utilization of glucose)
- Other conditions like, liver affections, vomiting in pregnancy, radiation sickness, disease of the skin and mucus membrane.
- In visual disturbances, and disease of the nervous system.

4. DOSAGE AND ADMINISTRATION

For severe illness, 1 ampoule I/M or I/V daily until the disappearance of acute symptoms, continue with 1 ampoule 2 – 3 times weekly, I/M, I/V or as prescribed by the physician.

5. CONTRAINDICATIONS

Polybion® Forte Ampoule is contraindicated in patients known to be hypersensitive to any of its components or pre-existing B hypervitaminosis. Dexpanthenol is contraindicated in hemophiliacs and in patients with ileus due to mechanical obstruction. Cyanocobalamin should not be administered for megaloblastic anemia caused by folate deficiency.

6. WARNINGS AND PRECAUTIONS

Rare cases of anaphylactic shock have been known to occur after parenteral administration of thiamine. A few unconfirmed allergic reactions have been noted from dexpanthenol and a rare number of allergic hypersensitivity reactions from administration of cyanocobalamin.

NOTE: Should Anaphylactic Shock occur, immediately stop administration of the product.

7. ADVERSE EFFECTS

Allergic reactions, including rash, pruritus, and anaphylaxis have been reported with Vitamin use. Components of this product have been associated with gastrointestinal effects such as heartburn, eructation, abdominal pain and cramps, diarrhea, vomiting, nausea, and anorexia. Hepatic dysfunction with abnormal liver function tests, including hyperbilirubinemia has been noted. Deterioration of acroiform vulgaris, or eruption of acroiform exanthema, has been noted with several components. Bright yellow urine discoloration has been reported with riboflavin usage. Nicotinamide has strong vasodilator effects, most often characterized by flushing, dizziness, or

faintness, and chronic administration had various side effects such as headaches, hives, fatigue, sore throat and inability to focus eyes. Peripheral sensory neuropathies have been noted with the use of pyridoxine. However, risk appears to occur at doses above 1000 mg per day for long periods of time. Administration of doses greater than 10 µg daily of cyanocobalamin may produce a hematological response in patients with folate deficiency, indiscriminate use of cyanocobalamin may mask the precise diagnosis.

8. DRUG INTERACTIONS

With concomitant use of niacinamide and alcohol, toxic delirium and lactic acidosis have been noted. Concomitant use of niacinamide and nicotine has been reported to cause increased flushing and dizziness. Since pyridoxine is noted to have effects on dopamine, drug interactions are possible. A drug interaction with Levodopa is noted but can be avoided if Levodopa is given in combination with a decarboxylase inhibitor. Serum phenytoin and phenobarbital levels have been reported to decrease in patients receiving 80 to 200 mg/day of pyridoxine. Use of anticonvulsants and sulfasalazine has been associated with folate deficiency, even when folic acid is supplied orally. Prothrombin times are decreased when ascorbic acid is used concomitantly with anticoagulants.

9. PREGNANCY AND LACTATION

Not Known

10. SPECIAL POPULATIONS

Not known

11. CLINICAL PHARMACOLOGY

The B vitamins are critically tied to the metabolism of carbohydrates, amino acids and fats and are essential for the production of energy in cells, as well as carrying out many other functions. Deficiencies of one or more B vitamins may occur in debilitated states, with inadequate diet, with gastrointestinal pathologies, in alcoholism and the elderly. Deficiencies of several of the B vitamins are associated with severe neurological and skin disorders. The same disease condition in the body may result from the decreased level of just one of the B vitamins, or indeed from a simultaneous decrease in several of the B vitamins. Except in rare cases of metabolic disorders affecting a single vitamin, it is unusual for a person to have a deficiency of one B vitamin without a deficiency of others. The B vitamins are synergistic in metabolism and as such it is recommended that they are administered together.

12. OVERDOSAGE

No cases of hypervitaminosis have been reported even after several years of high-dose intake.

12.1 Toxicology

Vitamin B1: The toxic intravenous dose varies from 125 mg/kg for the rat to 350 mg/kg for the dog; the toxic oral dose is about 40 times higher. Clinically there have been occasional reports of toxic reactions following parenteral administration, probably due to hypersensitivity.

Vitamin B2: Virtually non-toxic. Oral administration of 10 g/kg to rats and 2 g/kg in dogs showed no toxic effects.

Vitamin B3 (Niacinamide): Nothing specific reported for niacinamide.

Vitamin B5 (Pantothenyl Alcohol): Essentially non-toxic. For calcium Pantothenate, no significant changes in blood pressure, pulse, temperature, nor respiration were observed in 15 people receiving intravenous doses of 100 mg of Pantothenate, in either the calcium or sodium form.

Vitamin B6 (Pyridoxine HCl): Large doses in the range of 3 to 4 g/kg produce convulsions and death in animals; lower doses may be administered without obvious effects.

Vitamin B12 (Cyanocobalamin): Essentially non-toxic. Intravenous injections of 1.6 g/kg of crystalline vitamin B12 produced no toxic effects in mice. Clinically, injections of crystalline B12 are painless and generally caused no untoward local reactions. Intramuscular and subcutaneous doses as large as 1000 mcg and intravenous doses as high as 3000 mcg have been administered without side effects.

13. HOW SUPPLIED

Presentation

Polybion® Forte Injection : Available pack of 25 x 2 ml ampoules

Storage

Store below 30°C.

Protect from light and heat.

Keep all medicines out of the reach of children.

Innovator's Specs.

Manufactured by:

Martin Dow Marker Ltd
7, Jail Road, Quetta, Pakistan,
13003679

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

رشتی اور گرمی سے محفوظ رکھیں۔

تمام دواؤں بچوں کی پہنچ سے دور رکھیں۔