



CBNT

## Pizotifen Vitamin B-Complex

	Per Capsule	Per 5 mL Syrup
Pizotifen	500 mcg	250 mcg
Thiamine (Vit. B <sub>1</sub> )	3 mg	700 mcg
	(as mononitrate)	(as hydrochloride)
Riboflavin phosphate (Vit. B <sub>2</sub> )	3.2 mg	1.14 mg
Pyridoxine hydrochloride (Vit. B <sub>6</sub> )	2.4 mg	700 mcg
Nicotinamide	19 mg	5 mg

## Mosegor Vita

**Dear Patient,**  
Please read the following instructions carefully.  
They contain important information about the use of this drug.  
If you have any further questions, please ask your pharmacist or doctor.



### FORMULATION:

	Per Capsule	Per 5 mL Syrup
Pizotifen (as hydrogen maleate)	500 mcg	250 mcg
Thiamine (Vit. B <sub>1</sub> )	3 mg	700 mcg
	(as mononitrate)	(as hydrochloride)
Riboflavin Phosphate (Vit. B <sub>2</sub> )	3.2 mg	1.14 mg
Pyridoxine hydrochloride (Vit. B <sub>6</sub> )	2.4 mg	700 mcg
Nicotinamide	19 mg	5 mg

### PROPERTIES:

Pizotifen has an appetite-stimulating action suitable for increasing body weight in underweight anorectic patients. The compound is well tolerated, permitting treatment of anorexia both in children and adults.

Owing to its inhibitory effect on biogenic amines, pizotifen is also used for the prophylactic (interval) treatment of migraine. The B-complex vitamins B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub> and nicotinamide prevent deficiencies of these vitamins often associated with inadequate food intake. Such a need may also arise from antibiotic or other drug therapy with vitamin utilization.

### PHARMACOKINETICS:

The absorption of pizotifen is fast (absorption half-life 0.5 - 0.8 hours)

and nearly complete (80%). The substance is metabolized with a half-life of about 1 hour. The main metabolite (N-glucuronide) is eliminated with a half-life approx. 23 hours. The protein binding amounts to 91% and the distribution volume to 48.5 L. less than 1% of the administered dose is excreted unchanged in urine, whereas 55% is excreted as metabolites. In patients with kidney insufficiency dosage adjustment may therefore be necessary.

### INDICATIONS:

Anorexia of somatic or psychogenic origin in underweight patients, in whom prevention of vitamin-B deficiency secondary to impaired dietary intake or absorption (e.g. as a consequence of antibiotics or other drug therapy interfering with absorption or utilization of B-group vitamins) is indicated. Priority should always be given to identifying and treating the underlying cause of anorexia, such as infectious or parasitic diseases, chronic diarrhea, anorexia nervosa or depressive states in the elderly.

### DOSAGE:

#### For Syrup:

Children: Small initial dose should be gradually increased to an average maintenance dosage of 0.025 mg. Pizotifen per kg. body weight daily e.g., 2 - 6 years: 10 - 20 mL

148.0 mm

daily in 2 or 3 divided doses or as directed by the physician.

**Adults:** Starting with 10 mL syrup per day, dosage should be progressively increased up to 10 mL syrup three times daily.

*Duration of therapy:* as directed by the physician.

### For Capsules:

**Adults:** Starting with 1 capsule per day, dosage should be progressively increased to 1 capsule three times daily.

*Duration of therapy:* as directed by the physician.

### CONTRAINDICATIONS:

Hypersensitivity to the drug.

Pizotifen + Thiamine HCl + Riboflavin phosphate + Pyridoxine HCl + Nicotinamide (Mosegor Vita) should not be given to children below 1 year of age.

### PRECAUTIONS:

Patients should be warned that, owing to its possible sedative effect, Pizotifen + Thiamine HCl + Riboflavin phosphate + Pyridoxine HCl + Nicotinamide (Mosegor Vita) may slow their reactions when driving vehicles, operating machinery, etc.

In view of the very slight anticholinergic effect of pizotifen, caution is required in patients with narrow-angle glaucoma (except those successfully treated by surgery) or urinary retention (e.g. in prostatic enlargement). Up to now no untoward reactions have been reported in such patients, not even in the elderly, when given the recommended dose. As clinical data with pizotifen in pregnancy are very limited, Pizotifen + Thiamine HCl + Riboflavin phosphate + Pyridoxine HCl + Nicotinamide (Mosegor Vita) should be administered in pregnancy only under compelling circumstances. Although the concentration of pizotifen measured in the milk of treated mothers are not likely to affect the infant, its use in nursing mothers is not recommended.

Pizotifen + Thiamine HCl + Riboflavin phosphate + Pyridoxine HCl + Nicotinamide (Mosegor Vita) should be kept out of the reach of children.

### INTERACTIONS:

Central effects of sedatives, hypnotics, antihistamines including certain common cold preparations, and alcohol may be enhanced.

### SIDE EFFECTS:

The most common side-effect is sedation; more rarely are dizziness, dry mouth, nausea, and constipation. In children, CNS stimulation may occur.

### OVERDOSAGE:

Symptoms which may be expected are: drowsiness, nausea, hypotension, dizziness, excitatory states (in children), coma. Treatment: gastric lavage followed by administration of activated charcoal. If necessary, symptomatic treatment including monitoring of the cardiovascular and respiratory system; for excitatory states or convulsion: benzodiazepines.

### STORAGE

(for Mosegor Vita Capsule) Store at temperatures not exceeding 30° C. (for Mosegor Vita Syrup) Store at temperatures not exceeding 25° C.

### CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: [www.fda.gov/ph](http://www.fda.gov/ph)  
The patient is advised to seek IMMEDIATE medical attention at the first sign of adverse drug reaction.

### AVAILABILITY

Capsules: Packs of 100's and 500's  
Syrup: Bottles of 60 mL and 120 mL

Manufactured by: **Interphil Laboratories, Inc.**, Canlubang Industrial Estate, Ba. Pitland, Cabuyao, Laguna  
For: **Sandoz Philippines Corporation**, 5th and 6th Floor Ayala North Exchange Tower 1 (HQ), Ayala Ave. cor. Salcedo and Amorsolo Sts.  
Irigay, San Lorenzo, Makati City

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