

## **VITAMIN B COMPLEX- thiamine hydrochloride, riboflavin 5 phosphate sodium, dexpanthenol and niacinamide injection**

**Mylan Institutional LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).*

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### **DESCRIPTION**

Vitamin B-Complex 100 Injection is a sterile solution for intramuscular or slow intravenous injection comprised of vitamins which may be categorized as belonging to the vitamin B complex group.

Each mL contains: Thiamine Hydrochloride 100 mg, Riboflavin 5' Phosphate Sodium 2 mg, Pyridoxine Hydrochloride 2 mg, Dexpanthenol 2 mg, Niacinamide 100 mg, with Benzyl Alcohol 2% as preservative, in Water for Injection. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH.

### **INDICATIONS AND USAGE**

In disorders requiring parenteral administration of vitamins, i.e. pre- and post-operative treatment, when requirements are increased as in fever, severe burns, increased metabolism, pregnancy, gastrointestinal disorders interfering with intake or absorption of vitamins, prolonged or wasting diseases, alcoholism and where other deficiencies exist.

### **CONTRAINDICATIONS**

Sensitivity to the ingredients listed.

### **WARNINGS**

Anaphylactogenesis may occur with parenteral thiamine. Use with caution. An intradermal test dose is recommended prior to administration in patients suspected of being sensitive to the drug.

### **PRECAUTIONS**

The usual precautions for parenteral administration should be observed. Do not inject if precipitation occurs. Inject slowly by the intravenous route. High concentrations should be diluted using Normal Saline Injection when given intravenously.

### **ADVERSE REACTIONS**

Mild transient diarrhea, polycythemia vera, peripheral vascular thrombosis, itching transitory exanthema, feeling of swelling of entire body, anaphylactic shock and death. Sensitivity to the ingredients listed may occur (see **WARNINGS**). Use should be discontinued upon observance of any untoward reaction. Pain upon intramuscular injection may be noted.

### **DOSAGE AND ADMINISTRATION**

Usually 0.25 to 2 mL by intramuscular or slow intravenous injection. High concentrations given intravenously may be diluted using parenteral infusion solutions. (See **PRECAUTIONS**.)

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit (see **HOW SUPPLIED**).

## HOW SUPPLIED

Vitamin B-Complex 100 Injection is available in a 30 mL multiple-dose vial individually boxed.

Phase separation due to reduced solubility can occur under certain conditions of shipping or storage (e.g. accidental freezing), which may produce visible particles. Do not use product if these do not redissolve on warming to body temperature and shaking well.

Refrigeration of the product may cause darkening of the solution due to the riboflavin content. The colour does not affect the safety or efficacy of the product.

**PROTECT FROM LIGHT:** Store in carton until contents are used. Store under refrigeration 2° to 8°C (36° to 46°F). Do not permit to freeze.

Manufactured for:

**Mylan Institutional LLC**  
Rockford, IL 61103 U.S.A.

Manufactured by:

**Mylan Institutional**  
Galway, Ireland

0415L106

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MI:VITBIJ:R3

## PRINCIPAL DISPLAY PANEL - 30 mL

**NDC 67457-146-30 30 mL**

**Vitamin  
B-Complex  
100 Injection**

**For Intramuscular or  
Slow Intravenous Use**

**Rx only Multi-Dose Vial**

Sterile

**Each mL contains:** Thiamine HCl  
100 mg, Riboflavin 5' Phosphate  
Sodium 2 mg, Pyridoxine HCl  
2 mg, Dexpanthenol 2 mg,  
Niacinamide 100 mg, with Benzyl  
Alcohol 2% as preservative, in  
Water for Injection. Sodium  
Hydroxide and/or Hydrochloric  
Acid may have been used to  
adjust pH.

**Warning:** Anaphylactogenesis to  
parenteral thiamine has been  
reported.

Use with caution.

**Usual Dosage:** See accompanying

prescribing information.

**STORE UNDER  
REFRIGERATION 2° TO 8°C  
(36° TO 46°F).**

**DO NOT FREEZE.**

**Protect from light.**

Store in carton until contents are used.

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**Mylan.com**



## VITAMIN B COMPLEX

thiamine hydrochloride, riboflavin 5 phosphate sodium, dexpantenol and niacinamide injection

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67457-146
Route of Administration	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	100 mg in 1 mL
<b>RIBOFLAVIN 5'-PHOSPHATE SODIUM</b> (UNII: 20RD1DZH99) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E)	FLAVIN MONONUCLEOTIDE	2 mg in 1 mL
<b>DEXPANTHENOL</b> (UNII: 1O6C93RI7Z) (DEXPANTHENOL - UNII:1O6C93RI7Z)	DEXPANTHENOL	2 mg in 1 mL
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	100 mg in 1 mL
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	2 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	20 mg in 1 mL
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67457-146-30	1 in 1 CARTON	05/10/2013	
1		30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/10/2013	

**Labeler** - Mylan Institutional LLC (790384502)

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