

VITAMIN B COMPLEX- thiamine hydrochloride, riboflavin 5'-phosphate sodium, dexpanthenol, niacinamide and pyridoxine hydrochloride 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](#).

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

0415L105

REVISED OCTOBER 2012
MI:VITBIJ:R2

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

Manufactured for:

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

Manufactured by:

Mylan Institutional
Galway, Ireland

MI:146:1C:R2

Mylan.com

Sterile

Each mL contains: Thiamine HCl
100 mg, Riboflavin 5' Phosphate
Sodium 2 mg, Pyridoxine HCl
2 mg, Dextranthenol 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.



VITAMIN B COMPLEX

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

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
THIAMINE HYDROCHLORIDE (THIAMINE ION)	THIAMINE	100 mg in 1 mL
RIBOFLAVIN 5'-PHOSPHATE SODIUM (RIBOFLAVIN)	RIBOFLAVIN	2 mg in 1 mL
DEXPANTHENOL (DEXPANTHENOL)	DEXPANTHENOL	2 mg in 1 mL
NIACINAMIDE (NIACINAMIDE)	NIACINAMIDE	100 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (PYRIDOXINE)	PYRIDOXINE HYDROCHLORIDE	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL	20 mg in 1 mL
WATER	
HYDROCHLORIC ACID	
SODIUM HYDROXIDE	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67457-146-30	1 in 1 CARTON		
1		30 mL in 1 VIAL, MULTI-DOSE		

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)

Revised: 3/2012

Mylan Institutional LLC