VITAMIN B COMPLEX- thiamine hydrochloride, riboflavin 5 phosphate sodium, pyridoxine hydrochloride, dexpanthenol and niacinamide injection, solution
Raw Materials International Overseas 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.

Vitamin B complex

Thiamine hydrochloride, riboflavin 5 phosphate sodium, dexpanthenol, niacinamide and pyridoxine injection

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.

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.

Sensitivity to the ingredients listed.

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.

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.

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.

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).

Vitamin B-Complex 100 Injection

Rx Only

NDC 69877-026-01 30 mL Multi-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:

Raw Materials International Overseas LLC
Miami Beach, FL 33140

United States

Rev. 07/15

VITAMIN B COMPLEX

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69877-026
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20RD1DZH99) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	2 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	2 mg in 1 mL
DEXPANTHENOL (UNII: 1O6C93RI7Z) (DEXPANTHENOL - UNII:1O6C93RI7Z)	DEXPANTHENOL	2 mg in 1 mL
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	100 mg in 1 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	20 mg in 1 mL
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69877-026-01	1 in 1 BOX		
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		07/06/2015	

Labeler - Raw Materials International Overseas LLC (079829477)

Revised: 12/2015 Raw Materials International Overseas LLC