VITAMIN B COMPLEX- thiamine hydrochloride, riboflavin 5 phosphate sodium, dexamethasone 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.

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, Dexamethasone 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
Revised: 10/2017
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, Dextropanthenol 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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MI:146:1C:R3

Mylan.com
VITAMIN B COMPLEX
thiamine hydrochloride, riboflavin 5 phosphate sodium, dextanethenol and niacinamide injection

<table>
<thead>
<tr>
<th>Product Information</th>
</tr>
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<tbody>
<tr>
<td><strong>Product Type</strong></td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
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<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)</td>
<td>THIAMINE</td>
<td>100 mg in 1 mL</td>
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<tr>
<td>RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20RD1DZH9) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E)</td>
<td>FLAVIN MONONUCLEOTIDE</td>
<td>2 mg in 1 mL</td>
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<tr>
<td>DEXPANTHENOL (UNII: 1O6C93RI7Z) (DEXPANTHENOL - UNII:1O6C93RI7Z)</td>
<td>DEXPANTHENOL</td>
<td>2 mg in 1 mL</td>
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<tr>
<td>NIACINAMIDE (UNII: 25X518RD4) (NIACINAMIDE - UNII:25X518RD4)</td>
<td>NIACINAMIDE</td>
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<tr>
<td>PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)</td>
<td>PYRIDOXINE HYDROCHLORIDE</td>
<td>2 mg in 1 mL</td>
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### Inactive Ingredients

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

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

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<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>Unapproved drug other</td>
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**Labeler** - Mylan Institutional LLC (790384502)

Revised: 10/2017