

**B-PLEX 100- thiamine hydrochloride, riboflavin 5-phosphate sodium, pyridoxine hydrochloride, dexpanthenol, niacinamide injection, solution**

**Merit Pharmaceutical**

*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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**B PLEX 100**

**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 100mg, Riboflavin 5' Phosphate Sodium 2mg, Pyridoxine Hydrochloride 2mg, Dexpanthenol 2mg, 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 30mL 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.

**Rx Only**

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

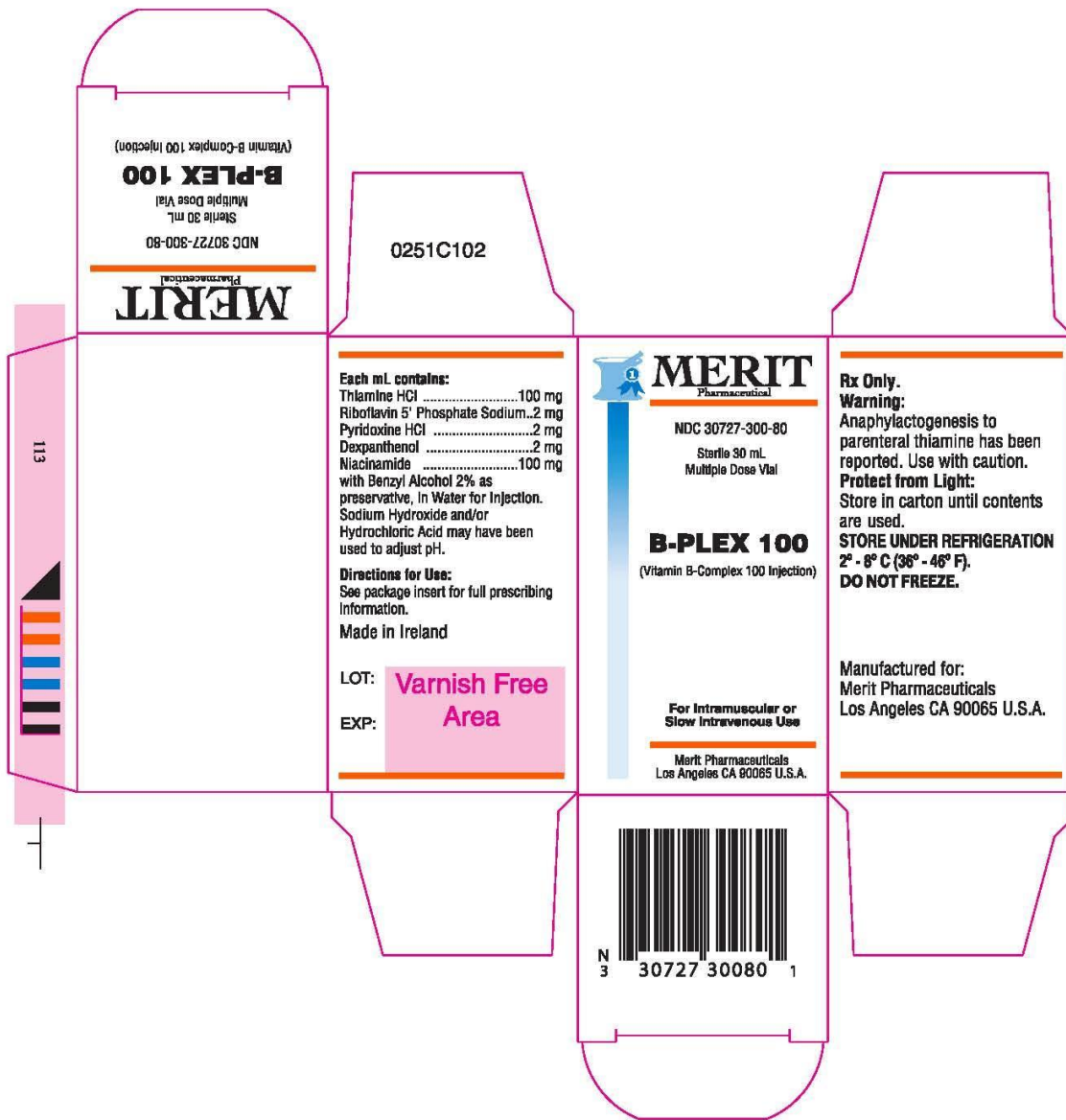
Manufactured for:  
 Bioniche Pharma USA LLC,  
 Lake Forest, IL 60045


Manufactured by:  
 Bioniche Teo.,  
 Inverin, Co. Galway, Ireland

Date Prepared: July 2001

Revised: May 2007

0415L103



	<b>Customer</b> - Bioniche <b>Description</b> - Merit B-Complex <b>Code Ref</b> - 0251C102 <b>Cutter Ref</b> - Bion27 B#-#1 <b>Size</b> - 39 x 39 x 71	<b>PMS 3005</b> <b>PMS 021</b> <b>Black</b>	<table border="1"> <tr> <td>APPROVED &amp; PRICED</td> <td>AMEND &amp; RE-SUBMIT</td> <td>MANUFACTURE</td> </tr> <tr> <td></td> <td></td> <td>CHANGING</td> </tr> <tr> <td></td> <td></td> <td>ON ONE PAGE</td> </tr> <tr> <td></td> <td></td> <td>AND RETURN</td> </tr> </table>	APPROVED & PRICED	AMEND & RE-SUBMIT	MANUFACTURE			CHANGING			ON ONE PAGE			AND RETURN
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<b>CHESAPEAKE</b> Raheen Business Park Raheen, Limerick Tel: +35361303500 Fax: +35361304100 ISDN +353 0 61 480012	<b>Proof No.</b> - 3 <b>Proof By</b> - L. Ryan <b>Date</b> - 16/4/2009 <b>EMS Code</b> - 113 <b>Pharma Code</b> - NA	PRINT NAME _____ DATE _____
	KEYLINE VFA	
	<b>PLEASE REFER TO AGREED COLOUR STANDARDS/PANTONE REFERENCE FOR COLOUR MATCH</b> <small>Your artwork has been translated through our Digital Artwork System into a format compatible with that of the Litho Printing Process.          PLEASE READ THIS IMPORTANT INFORMATION: Please ensure this proof matches your artwork requirements. Please check ALL aspects of the proof i.e. text, fonts, spelling, colour, size, construction, copy position, barcodes, pharma codes, orientation of graphic etc. Mark clearly any amendments required. Receiving the approval of this proof will authorise Chesapeake to proceed with your order. Chesapeake will not be liable for the costs of an order produced where any amendments required were not identified on the signed proof. Please return the signed approval at your earliest convenience to enable us to proceed with the order and meet your requested delivery date.</small>	

## B-PLEX 100

thiamine hydrochloride, riboflavin 5-phosphate sodium, pyridoxine hydrochloride, dexpantanol, niacinamide injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:30727-300
<b>Route of Administration</b>	INTRAMUSCULAR, INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	100 mg in 1 mL
RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20RD1DZH99) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E)	FLAVIN MONONUCLEOTIDE	2 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	2 mg in 1 mL
DEXPANTHENOL (UNII: 106C93RI7Z) (DEXPANTHENOL - UNII:106C93RI7Z)	DEXPANTHENOL	2 mg in 1 mL
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

### Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30727-300-80	1 in 1 CARTON	01/01/2012	
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		01/01/2012	

**Labeler** - Merit Pharmaceutical (093370369)

**Registrant** - Merit Pharmaceutical (093370369)

Revised: 11/2017

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