

**NITROVAL BLUE- menthol cream**  
**PLUM VALLEYPHARMA LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**NitroVal Blue cream**

**Drug facts**

**Active ingredients:**

Menthol USP 3.7%

**Purpose**

Topical analgesic

**Uses** Temporary relief from minor aches and pains of sore muscles & Joints associated with arthritis, simple backache, strains, bruises & sprains.

**Warnings**

**For external use only.** Keep away from excessive heat or flame.

**When using this product**

- Avoid contact with the eyes or mucous membranes not apply to wounds or damaged skin.
- Do not use with other ointments, creams, sprays, or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandaged not use with heating pad or device
- Wash hands after use with cool water

**Stop use and ask a doctor if**

Condition worsens, or if symptoms persist for more than 7 days, or clear up and return.

**Warnings**

**If pregnant or breast-feeding:** Ask a health professional before use.

Keep out of reach of children: If accidentally ingested, get medical help or contact Poison Control Center immediately.

**Other:** Store in a cool dry place. Close cap tightly.

**Directions:**

- Adults and children 12 years of age and older:  
Apply and massage onto affected areas. Repeat as needed no more than 4 times daily. Wash hands after use with cool water.
- **Children under 12 years of age:** Consult physician.

**Inactive Ingredients:** Aloe Barbadosis Leaf Extract, Arnica Montana Flower Extract, Carbomer, Dimethyl Sulfone (MSM), EDTA, FDC Blue #1, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Melaleuca

Alternifolia (Tea Tree) Leaf Oil, Pyridoxine HCl (Vitamin B6),  
Phenoxyethanol & Methyl/Ethyl/Butyl/Propyl/Isobutyl parabens,  
Polysorbate 20, Purified Water, Tocopheryl (Vitamin E) Acetate,  
Triethanolamine

Manufactured For:  
Plum Valley Pharma, LLC  
Dear born, MI 48120 USA  
Questions and Information please call  
**Toll Free: 866-248-1553**

NDC: 82226-160-85 For Topical Use Only

**NitroValBLUE**

**Pain Relief Cream**

Plum  
Valley Pharma

Net Wt. 3 oz. (85g) Topical Analgesic

Made in USA

Manufactured For:  
Plum Valley Pharma, LLC  
Dear born, MI 48120 USA  
Questions and Information please call  
**Toll Free: 866-248-1553**

<p><b>Drug Facts Continued</b></p> <p><b>Warnings</b> If pregnant or breast-feeding: Ask a health professional before use. Keep out of reach of children: If accidentally ingested, get medical help or contact Poison Control Center immediately. Other: Store in a cool dry place. Close cap tightly.</p> <p><b>Directions: •Adults and children 12 years of age and older:</b> Apply and massage onto affected areas. Repeat as needed no more than 4 times daily. Wash hands after use with cool water. •Children under 12 years of age: Consult physician.</p> <p><b>Inactive Ingredients:</b> Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Carbomer, Dimethyl Sulfoxide (MSM), EDTA, FDC Blue #1, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Pyridoxine HCl (Vitamin B6), Phenoxyethanol &amp; Methyl/Ethyl/Butyl/Propyl/Isobutyl parabens, Polysorbate 20, Purified Water, Tocopheryl (Vitamin E) Acetate, Triethanolamine</p>	<p>NDC: 82226-160-85</p> <p>For Topical Use Only</p>  <p><b>NitroVal</b><sup>BLUE</sup> Pain Relief Cream</p> <p>Net Wt. 3 oz. (85g) Topical Analgesic</p> <p>Plum Valley Pharma logo, Not Tested on Animals logo, Made in USA logo, and manufacturer information.</p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active Ingredients:</b> Menthol USP 3.7%</td> <td><b>Purpose</b> Topical Analgesic</td> </tr> </table> <p><b>Uses</b> Temporary relief from minor aches and pains of sore muscles &amp; joints associated with arthritis, simple backache, strains, bruises &amp; sprains.</p> <p><b>Warnings:</b> Use only as Directed For external use only. Keep away from excessive heat or flame. When using this product: Avoid contact with the eyes or mucous membranes not apply to wounds or damaged skin •Do not use with other ointments, creams, sprays, or liniments •Do not apply to irritated skin or if excessive irritation develops •Do not bandage and not use with heating pad or device •Wash hands after use with cool water <b>Stop use and ask doctor if:</b> Condition worsens, or if symptoms persist for more than 7 days, or clear up and return.</p>	<b>Active Ingredients:</b> Menthol USP 3.7%	<b>Purpose</b> Topical Analgesic
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**NITROVAL BLUE**

menthol cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82226-160
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.7 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B404F)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>2-(2-(2-(2-PHENOXYETHOXY)ETHOXY)ETHOXY)ETHANOL</b> (UNII: Y050HYR4XA)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MELALEUCA ALTERNIFOLIA LEAF</b> (UNII: G43C57162K)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82226-160-85	85 g in 1 JAR; Type 0: Not a Combination Product	06/21/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/21/2022	

**Labeler** - PLUM VALLEYPHARMA LLC (118243219)

Revised: 6/2022

PLUM VALLEYPHARMA LLC