

DR. BLUE- menthol gel
Indiana Botanic Gardens

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.

Dr. Blue

Drug Facts

Active Ingredient

Menthol 4.6%

Purpose

topical analgesic gel

Uses

■ temporary relief of minor aches and pains of muscles & joints associated with simple backache, arthritis, bruises and sprains ■ provides cooling pain relief

Warnings

For external use only

When using this product

■ Do not heat ■ Do not microwave ■ Do not use near open flame ■ Do not add to hot water or any container when heating water. May cause splattering and result in burns. ■ Avoid contact with eyes ■ Do not apply to wounds or damaged skin ■ Do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- See the important warnings under "when using this product"
- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: consult physician.

Other Information:

Use only if seal is unbroken.

Inactive Ingredients

Aloe Vera Concentrate, Carbopol-940, Emu Oil, FD&C Blue #1, Glucosamine Sulfate, Glycerin, Green tea Fragrance, Imidazolidinyl Urea, MSM Powder, Propylene Glycol, SDA Alcohol 39B, Triethanolamine, Water

Questions?

1-800-644-8327

Manufactured by Indiana Botanic Gardens, Inc

3401 W. 37th Ave. Hobart, IN 46342

website: www.botanicchoice.com

Pain Relieving Gel

Dr. Blue

For temporary relief of minor aches and pains of muscles and joints.

NDC 10578-035-05

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Dr. Blue™

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NET WT. 2 OZ.

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menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10578-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.89 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EMU OIL (UNII: 344821WD61)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
IMIDUREA (UNII: M629807ATL)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10578-035-03	71 g in 1 JAR		
2	NDC:10578-035-04	142 g in 1 JAR		
3	NDC:10578-035-05	57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2003	

Labeler - Indiana Botanic Gardens (005421771)

Establishment

Name	Address	ID/FEI	Business Operations
Indiana Botanic Gardens		005421771	manufacture(10578-035)

Revised: 9/2014

Indiana Botanic Gardens