

PAINZAWAY PAIN RELIEVING GEL- 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.

Painzaway Pain Relieving Gel

Active Ingredient

Menthol 4.6%

Purpose

topical analgesic

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 a physician.

Other Information:

Use only if seal is unbroken.

Inactive Ingredients

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

Questions?

1-800-644-8327

MANUFACTURED BY
INDIANA BOTANIC GARDENS, INC.
3401 W. 37TH AVE., HOBART, IN 46342
Website: BotanicChoice.com

PainzAway®

PAIN RELIEVING GEL

NET WT. 5 OZ.



PAINZAWAY PAIN RELIEVING GEL			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10578-135
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.6 g in 100 g	

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALCOHOL (UNII: 3K9958V90M)	
TEA LEAF OIL (UNII: VC855RRT77)	
IMIDUREA (UNII: M629807ATL)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
EMU OIL (UNII: 344821WD61)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10578-135-05	57 g in 1 JAR; Type 0: Not a Combination Product	04/19/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/19/2022	

Labeler - Indiana Botanic Gardens (005421771)

Registrant - Indiana Botanic Gardens (005421771)

Establishment

Name	Address	ID/FEI	Business Operations
Indiana Botanic Gardens		005421771	manufacture(10578-135)

