NUMOTIZINE - menthol ointment
Hobart Laboratories, Inc.

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.

NUMOTIZINE OINTMENT

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Active Ingredients

Menthol 1.25%

Purpose

Topical Analgesic

Inactive ingredients

Clay, Color, Fragrance of Guaiacol, Methyl Guaiacol and Oil of Wintergreen, Polyols.

Directions

Stir in any liquid at top of jar. Keep sealed when not in use.

Spread 1/8" to 1/4" of ointment to the skin. Cover the ointment with a cloth or bandage to protect clothing. Remove with warm water before totally dry (usually 8 to 12 hours). Application may be repeated every 12 hours as needed.

Uses

For use as a topical analgesic

- Provides temporary relief of muscle pain, soreness and stiffness
- Temporary pain relief on strains, sprains, ligament and tendon injuries
- Arthritis

Stop use and ask a doctor if

- Excessive irritation of the skin occurs.
- Persistent swellings.

Keep out of the reach of children

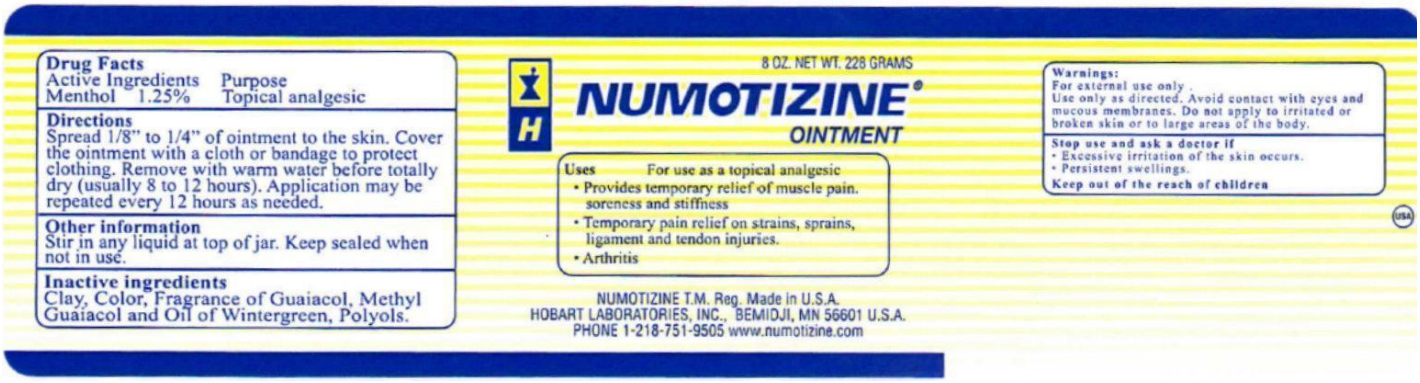
Warnings:

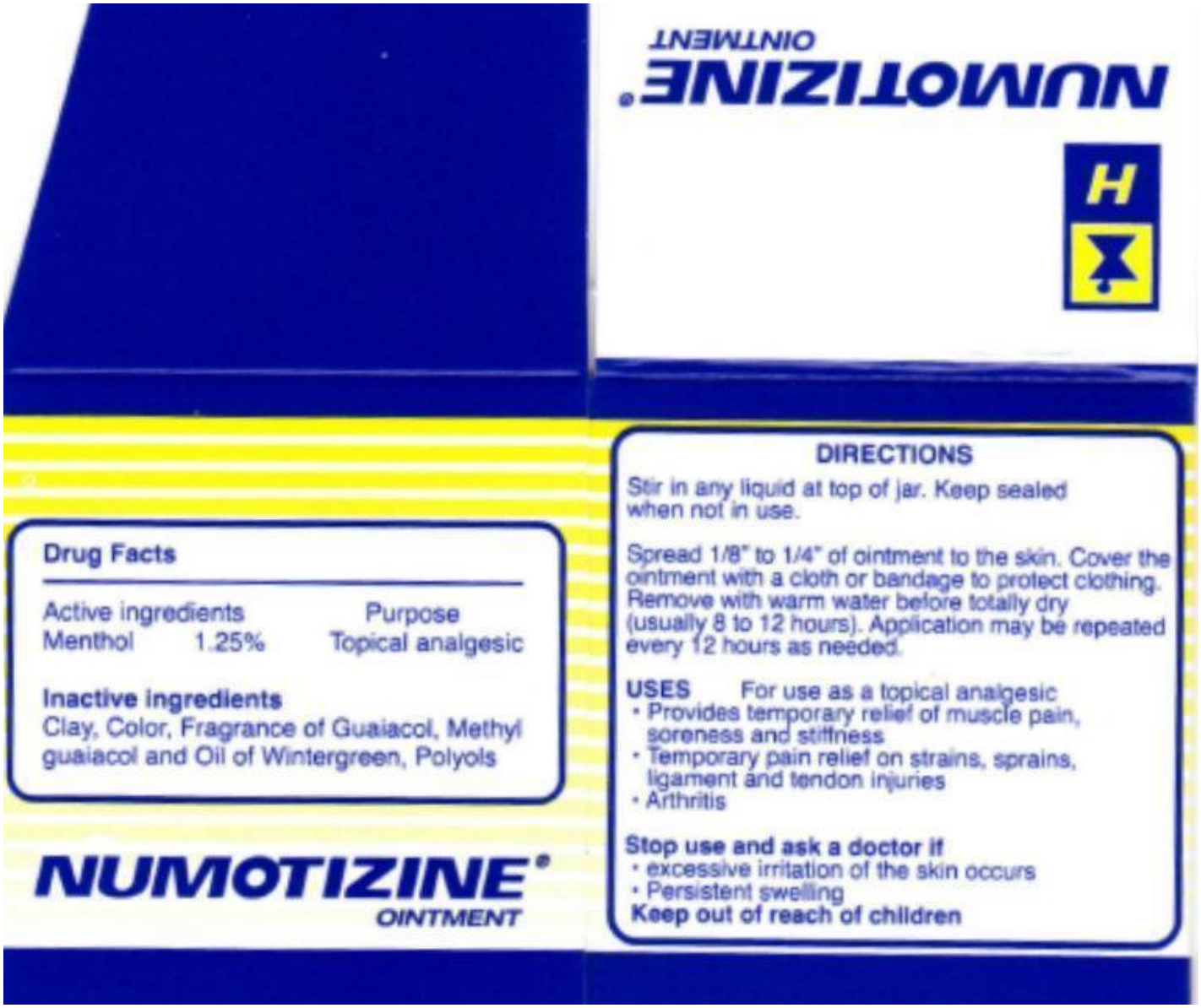
For external use only.

Use only as directed. Avoid contact with eyes and mucous memebranes.

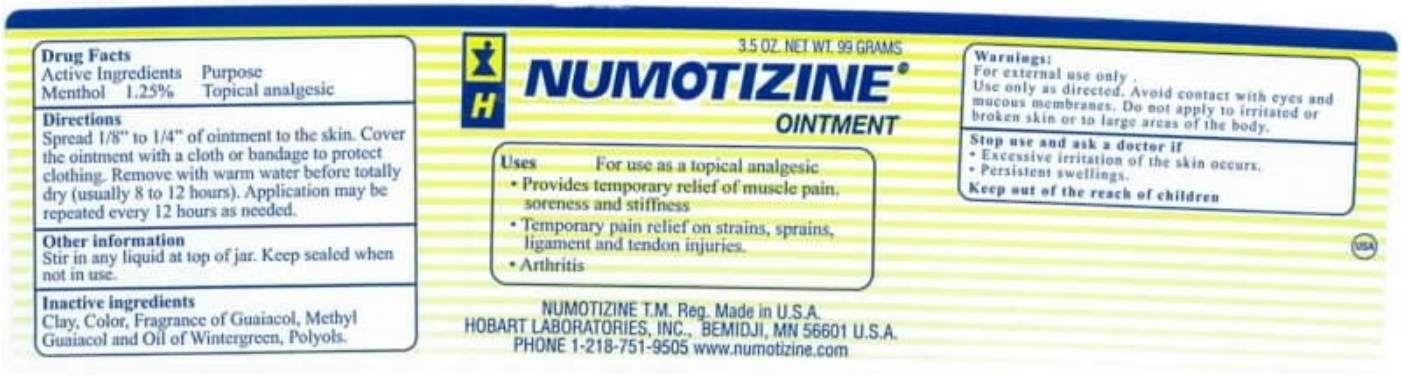
Do not apply to irritated or broken skin or to large areas of the body.

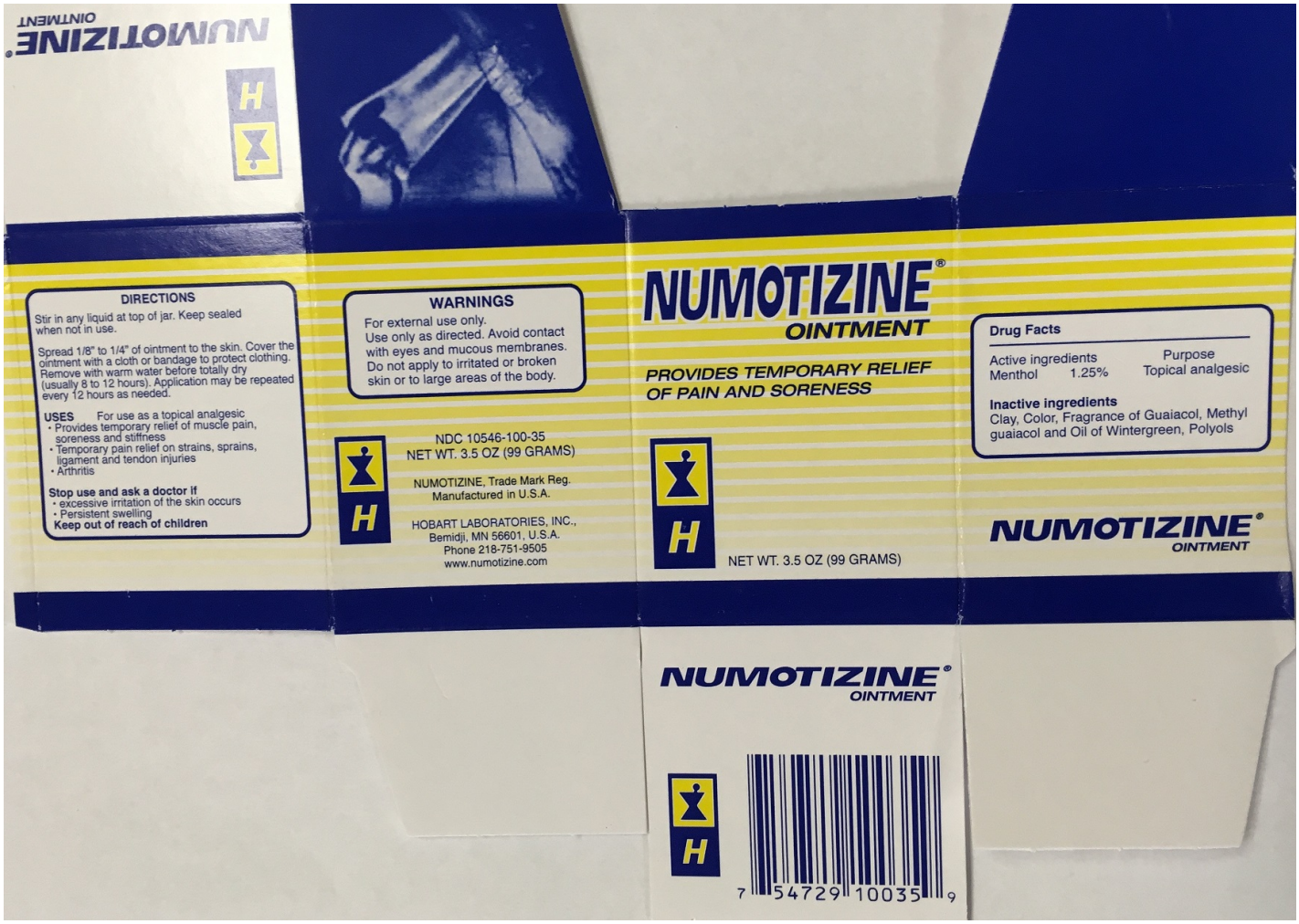
Representative Labeling For - Numotizine Ointment 3.5oz/99g (10546-100-35) | Numotizine Ointment 8oz/228g (10546-100-08)





Package Labeling:





NUMOTIZINE

menthol ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10546-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
KAOLIN (UNII: 24H4NWX5CO)	
GUAIACOL (UNII: 6JKA7MAH9C)	
CREOSOL (UNII: W9GW1KZG6N)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10546-100-35	99 g in 1 JAR; Type 0: Not a Combination Product	11/30/2011	
2	NDC:10546-100-08	228 g in 1 JAR; Type 0: Not a Combination Product	11/30/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/30/2011	

Labeler - Hobart Laboratories, Inc. (005111786)

Registrant - Hobart Laboratories, Inc. (005111786)

Establishment

Name	Address	ID/FEI	Business Operations
Hobart Laboratories, Inc.		005111786	manufacture(10546-100)

Revised: 9/2019 Hobart Laboratories, Inc.