LANDER POLAR ICE- menthol gel Abaco Partners LLC DBA Surefil

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.

LANDER®
POLAR ICE
TOPICAL ANALGESIC GEL

Drug Facts

Active Ingredients

Menthol, 2.0%

Purpose

Topical analgesic

Uses

Temporarily relieves:

- Minor muscle aches and pains

Warnings

For external use only; avoid contact with eyes

When using this product, do not;

- heat
- microwave
- add to hot water or any container where heating water may cause splattering and result in burns
- use in eyes or directly on mucous membranes take by mouth or place in nostrils
- apply to wounds or damaged skin
- bandage skin

Consult a doctor and discontinue use:

If condition worsens, persists for more than 1 week or tends to recur.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center Immediately.

Directions

For the temporary relief of minor muscle aches and pains. See important warnings under "**When using this products**"

- not for use on children under 2 years of age
- adults & children 2 years & older: apply liberally to painful area and massage until gel is absorbed into the skin. Repeat 3 to 4 times daily.

Inactive Ingredients

FD&C Blue #1, Camphor, Carbomer, Isopropyl Alcohol, Methylchloroisothiazolinone, Methylisothiazolinone, Nonoxynol - 9, Propylene Glycol, Sodium Hydroxide, Water.

Polar Ice $^{\circledR}$ is a registered trademark of Grand Brands LLC, Grand Rapids, MI 49512 USA

UPC: 8-14344-0-1123-9

PRINCIPAL DISPLAY PANEL - 226g Container

LANDER®

America's Health & Beauty Care Company

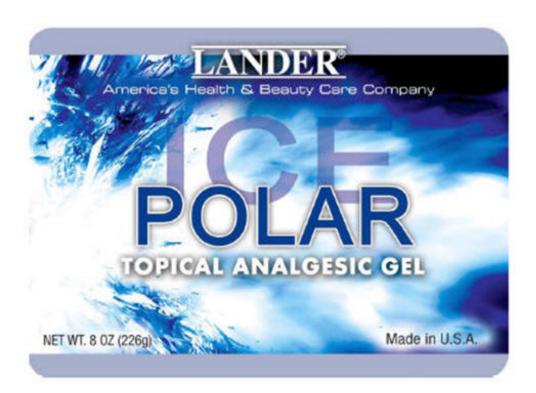
POLAR

ICE

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NET WT. 8 OZ (226g)

Made in U.S.A.



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LANDER POLAR ICE

menthol gel

Prod	4	TC-		.
Pron	uct	Into	rma	ntinn

Product Type HUMAN OTC DRUG Item Code (Source) NDC:208	90-0020
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	20 mg in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				
Propylene Glycol (UNII: 6DC9Q167V3)				
Camphor (SYNTHETIC) (UNII: 5TJD82A1ET)				
Nonoxynol-9 (UNII: 48Q180SH9T)				
Isopropyl Alcohol (UNII: ND2M416302)				
Carbomer Homopolymer Type C (UNII: 4Q93RCW27E)				
Sodium Hydroxide (UNII: 55X04QC32I)				
FD&C Blue NO. 1 (UNII: H3R47K3TBD)				
Methylchloroisothiazolinone (UNII: DEL7T5QRPN)				
Methylisothiazolinone (UNII: 229 D0 E1QFA)				

Product Characteristics				
Color	BLUE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20890-0020-1	226 g in 1 CONTAINER		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part356	12/0 1/20 10		

Labeler - Abaco Partners LLC DBA Surefil (964809417)

Establishment				
Name	Address	ID/FEI	Business Operations	
Anicare Pharmaceutical Pvt.		916837425	MANUFACTURE	

Revised: 10/2010 Abaco Partners LLC DBA Surefil