ARCTIC ICE- menthol gel
PRIMAL ELEMENTS

Active Ingredient:

Menthol, 1.25%

Purpose

Topical analgesic

Uses:

temporarily relieves:

minor muscle aches and pains

Warnings:

For external use only; avoid contact with eyes.

Ask a doctor before use if you have cough associated with smoking, excessive phlegm, asthma, emphysema, persistent or chronic cough.

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 product"

- 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:

Blue 1, Camphor, Carbomer, Ethyl Alcohol, Methylchoroisothiazolinone, Methylisothiazolinone, Sodium Hydroxide, Water.

ARCTIC ICE

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80801-105
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**
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER 934 (UNII: Z135WT9208)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80801-105-01	198 g in 1 JAR; Type 0: Not a Combination Product	10/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/01/2023	

Labeler - PRIMAL ELEMENTS (968334144)

Revised: 10/2023 PRIMAL ELEMENTS