

MINERAL ICE PAIN RELIEVING- menthol gel
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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.

Drug Facts

Active ingredient

Menthol 2%

Purpose

Topical analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
 - arthritis
 - simple backache
 - strains
 - bruises
 - sprains
- provides cooling penetrating relief

Warnings

For external use only

Do not use

- with other topical pain relievers
- with heating pads or heating devices

When using this product

- do not use in or near the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use

Keep out of reach of children.

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

Directions

- clean affected area before applying 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: ask a doctor

Other information

- store at controlled room temperature 20° to 25°C (68° to 77°F), in a tightly closed container
- Store in a cool place
- do not use, pour, spill or store near heat or open flame

Inactive ingredients

ammonium hydroxide, carbomer, cupric sulfate, FD&C blue no. 1, isopropyl alcohol, magnesium sulfate, purified water, sodium hydroxide, thymol

Questions or comments?

call 1-800-328-5258

Principal Display Panel

NDC 0067-2067-16

Mineral Ice[®]

ORIGINAL

THERAPEUTIC

MENTHOL PAIN RELIEVING GEL

Greaseless

With **DEEPCOLD[®]** Pain Reliever

Net Wt 16oz (453.6g)

Distributed by: **GSK Consumer Healthcare**

Warren, NJ 07059

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12904



MINERAL ICE PAIN RELIEVING

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-2067
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	.02 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
CUPRIC SULFATE (UNII: LRX7AJ16DT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
THYMOL (UNII: 3J50XA376E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2067-35	99.2 g in 1 JAR; Type 0: Not a Combination Product	11/01/2011	04/30/2020
2	NDC:0067-2067-08	226.8 g in 1 JAR; Type 0: Not a Combination Product	11/01/2011	08/31/2020
3	NDC:0067-2067-16	453.6 g in 1 JAR; Type 0: Not a Combination Product	11/01/2011	08/31/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/01/2011	08/31/2020

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 11/2018

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC