

ABEJAS Y VIBORAS BRAND ROLL-ON- menthol gel
MENPER DISTRIBUTORS 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.

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Uses

- for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthristis, strains and sprains.

Warnings

For external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child 12 years of age and under
- over extensive areas of the body
- on irritated skin
- with a bandage
- with other ointments, creams, sprays or liniments

Ask a doctor before use if you have redness over the affected area.

When using this product

- wash hands after use with cool water
- avoid contact with eyes or mucous membranes
- do not bandage

Stop use and ask a doctor if

- condition worsens or symptoms persists for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children to avoid accidental poisoning. If swallowed, induce vomiting and call a physician or contact a Poison Control Center right away.

Directions

- use only as directed
- Adults and children over 12 years: rub a thin film over affected areas not more than 4 times daily: message not necessary.



ABEJAS Y VIBORAS BRAND ROLL-ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-703
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-703-03	1 in 1 CARTON	03/01/2021	
1		88 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2021	

Labeler - MENPER DISTRIBUTORS INC. (101947166)

Revised: 3/2021

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