MANCORE MUSCLE MEND ROLL-ON PAIN RELIEVER - histamine dihydrochloride lotion
R2 Distribution, 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.

MANCORE MUSCLE MEND ROLL-ON PAIN RELIEVER

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Active Ingredient / Purpose

Histamine DHCl 0.06% / External Analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with arthritis, backache and sprains

Warnings

Use only as directed. For external use only. Not intended for persons under the age 18.

When using this product:
- Avoid contact with eyes
- Do not bandage tightly
- Do not apply to open wounds or damaged skin

Stop use and ask a doctor if:
- symptoms persist for more than seven days
- you experience irritation, redness or discomfort

Directions:

Apply directly to effected area. Do not use more than four times per day.

Other information:

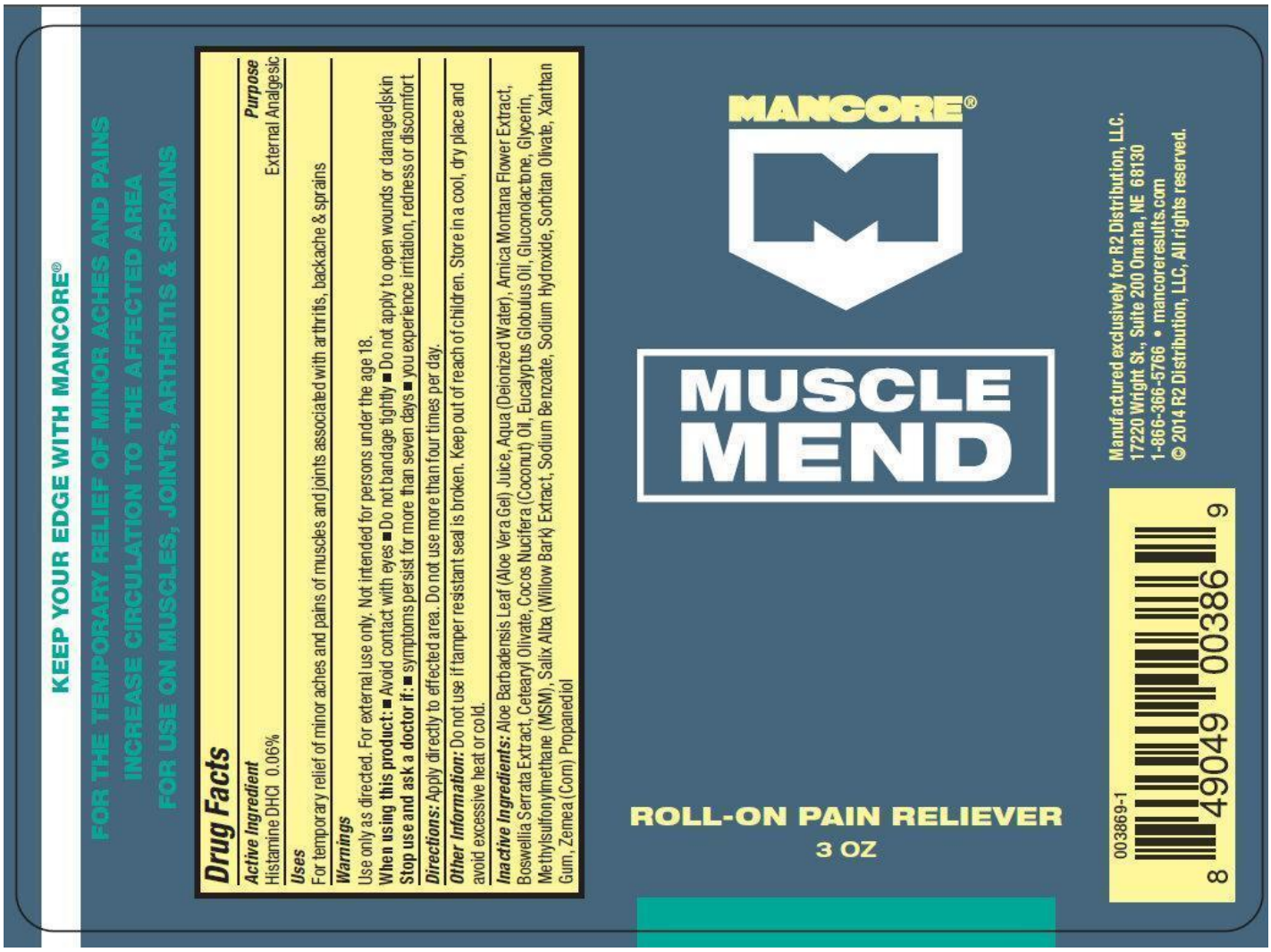
Do not use if tamper resistant seal is broken. Store in a cool, dry place and avoid excessive heat or cold.

Keep out of reach of children.

Inactive Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Olivate, Cocos Nucifera (Coconut) Oil, Eucalyptus Globulus Oil, Gluconolactone, Glycerin, Methylsulfonylmethane (MSM), Salix Alba (Willow Bark) Extract, Sodium Benzoate, Sodium Hydroxide, Sorbitan Olivate, Xanthan Gum, Zemea (Corn) Propanediol

MANCORE MUSCLE MEND ROLL-ON PAIN RELIEVER 3OZ (69198-700-85)



MANCORE MUSCLE MEND ROLL-ON PAIN RELIEVER

histamine dihydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69198-700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.6 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
COCONUT OIL (UNII: Q9L0O73W7L)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
WILLOW BARK (UNII: S883J9JDYX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69198-700-85	88.7206 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	02/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/27/2014	

Labeler - R2 Distribution, LLC (967077293)

Revised: 2/2017 R2 Distribution, LLC