

MYO-BREATHE- menthol gel

Myo-Breathe,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

Purpose: Topical Analgesic

Uses: Temporary relief from minor aches and pains of muscles and joints associated with: • simple backaches • arthritis • strains • bruises • sprains

Warning: For external use only

Flammable: Keep away from excessive heat or open flame

Ask a doctor before use if you have:

Sensitive skin

When using this product: • Use only as directed • Avoid contact with eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not bandage tightly or use with a heating pad

Stop use and ask a doctor if: Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again.

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: Adults and children 12 years of age and older:

Apply to affected area not more than 3 to 4 times daily.

Massage into painful area until thoroughly absorbed into skin

Children under 12 years of age: Consult a physician before use.

Questions or Comments? 1-800-803-1535

Penetrating Cooling Pain Relief From:

Muscle Strains & Sprains • Arthritis • Back Pain



Myo-Breathe[®]
Pain Relieving Gel

*Soothing Natural Aloe Vera Base
for Quick Absorbtion and Moisturizing Effect*

4 fl.oz. (118 ml)

Active Ingredient: Menthol 4%

MYO-BREATHE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41391-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMPHOR (natural) (UNII: N20HL7Q941)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBIC ACID (UNII: X045WJ989B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

Color	white (off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41391-119-11	5 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:41391-119-12	118 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:41391-119-13	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		
4	NDC:41391-119-19	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part348	01/10/2009	

