

MYO-BREATHE- menthol gel

Myo-Breathe

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 3.5%

Purpose(Topical Analgesic)

Uses

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

Warnings

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.

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

call 800-803-1535

Penetrating Cooling Pain Relief From:
Muscle Strains & Sprains, Arthritis, and Simple Backaches



Myo-Breathe[®]
Pain Relieving Gel

GREASELESS • NON-STAINING • VANISHING SCENT

Net Wt. 5g

Penetrating Cooling Pain Relief From:
Muscle Strains & Sprains • Arthritis • Simple Backaches



Myo-Breathe[®]
Pain Relieving Roll-On

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

3 fl. oz. (89 ml)

Penetrating Cooling Pain Relief From:

Muscle Strains & Sprains • Arthritis • Simple Backaches

Myo-Breathe[®] **Pain Relieving Gel**



4 fl. oz. (118 ml)

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

Penetrating Cooling Pain Relief From:
Muscle Strains & Sprains • Arthritis • Simple Backaches

Myo-Breathe[®] **Pain Relieving Gel**



32 fl.oz. (946 ml)

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

Penetrating Cooling Pain Relief From:
Muscle Strains & Sprains • Arthritis • Simple Backaches

Myo-Breathe[®] **Pain Relieving Gel**

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



128 fl. oz. (3784 ml)

MYO-BREATHE

menthol gel

Product Information

Product Type

HUMAN OTC DRUG LABEL

Item Code (Source)

NDC:4139 1-119

Route of Administration	TOPICAL	DEA Schedule	
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (MENTHOL)	Menthol	4000 mg in 4 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF	
CAMPHOR (natural)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES	
CARBOMER 934	
GLYCERIN	
ILEX PARAGUARIENSIS LEAF	
ISOPROPYL ALCOHOL	
LECITHIN, SOYBEAN	
DIMETHYL SULFONE	
PHENOXYETHANOL	
SORBIC ACID	
ALPHA-TOCOPHEROL ACETATE	

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		
2	NDC:41391-119-12	118 mL in 1 TUBE		
3	NDC:41391-119-13	89 mL in 1 BOTTLE, WITH APPLICATOR		
4	NDC:41391-119-14	946 mL in 1 BOTTLE, PUMP		
5	NDC:41391-119-15	3785 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/10/2009	

Labeler - Myo-Breathe (003635412)

