

## **MYO-BREATHE- menthol spray**

**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.*

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### **Drug Facts**

#### **Active Ingredient**

**Menthol 10.0%**

#### **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:

• Avoid contact with eyes or mucous • Use only as directed membranes • Do not bandage tightly or use a heating pad • Do not apply to wounds or damaged skin • Wash hands after use with cool water

*Stop use and ask a doctor if:*

Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again. • redness is present • excessive irritation of the skin develops.

#### **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:

Spray directly onto affected area not more than 4 times daily; without the need to massage or bandage • repeat as necessary • Children 12 years or younger: Consult a physician before use.

call 800-803-1535



## MYO-BREATHE

menthol spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41391-120
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA (UNII: O80TY208ZW)	
CAMPHOR (natural) (UNII: N20HL7Q941)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

### Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41391-120-16	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:41391-120-19	473 mL in 1 BOTTLE, SPRAY; 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	02/15/2015	

**Labeler** - Myo-Breathe,LLC (003635412)

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