

MUSCLE- menthol gel
WATER-JEL TECHNOLOGIES

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.

Muscle Jel

Active ingredient

Menthol 3.5%

Purpose

External analgesic

Uses

for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains

Warnings

For external use only

When using this product

- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- conditions worsens
- symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

Keep out of the reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Other information

- store at room temperature
- apply product directly onto sore areas of the body
- massage well for best results
- following application, wash hands well and rinse with cool water

Inactive ingredients

aloe barbadensis leaf juice, angelica archangelica root extract, camphor, carbomer, DMDM hydantoin, isopropyl alcohol, methylparaben, panax ginseng root extract, triethanolamine, water

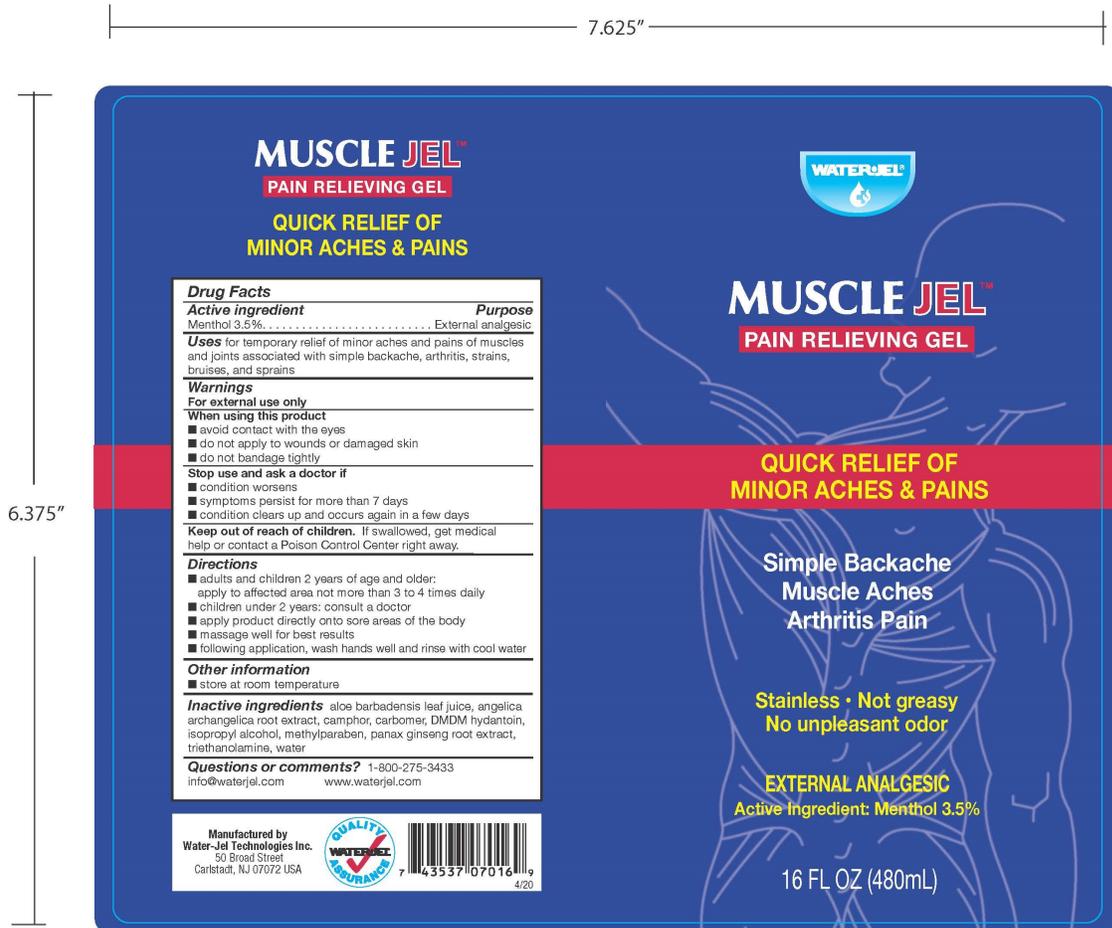
Questions?

1-800-275-343 info@waterjel.com www.waterjel.com

Manufactured by Water-Jel Technologies Inc.

50 Broad Street, Carlstadt NJ 07072 USA

Principal Display Panel



MUSCLE			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-805
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ANGELICA ARCHANGELICA ROOT (UNII: DTN01M69SN)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-805-17	1728 in 1 CARTON	04/19/2010	
1		3.8 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:59898-805-18	5 in 1 BOX, UNIT-DOSE	04/19/2010	
2		3.8 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:59898-805-05	96 in 1 BOX, UNIT-DOSE	04/19/2010	
3		3.8 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:59898-805-20	24 in 1 CARTON	04/19/2010	
4		3.8 mL in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:59898-805-24	3784 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/19/2010	
6	NDC:59898-805-21	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/19/2010	
7	NDC:59898-805-10	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/17/2013	
8	NDC:59898-805-23	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/19/2010	
9	NDC:59898-805-22	80 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/19/2010	
10	NDC:59898-805-25	118 mL in 1 TUBE; Type 0: Not a Combination Product	04/19/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/19/2010	

Labeler - WATER-JEL TECHNOLOGIES (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
WATER-JEL TECHNOLOGIES		155522589	manufacture(59898-805)

Revised: 12/2020

WATER-JEL TECHNOLOGIES