MENTHOLATUM PAIN RELIEVING- menthol, methyl salicylate lotion
The Mentholatum Company

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 ingredients

Menthol 6%

Methyl salicylate 20%

Purpose

Menthol - Topical analgesic

Methyl salicylate - Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to
- arthritis
- simple backache
- strains
- sprains

Warnings

For external use only

When using this product
- use only as directed
- do not get into eyes or on mucous membranes
- do not apply to wounds or to damaged skin
- do not bandage tightly
- do not use with a heating pad, other heat sources, or right after a shower/bath
- do not use in combination with other external analgesic products

Stop use and ask a doctor if
- condition worsens
- excessive irritation, burning or discomfort of the skin develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a healthcare professional before use.

Keep Out of Reach of Children.

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

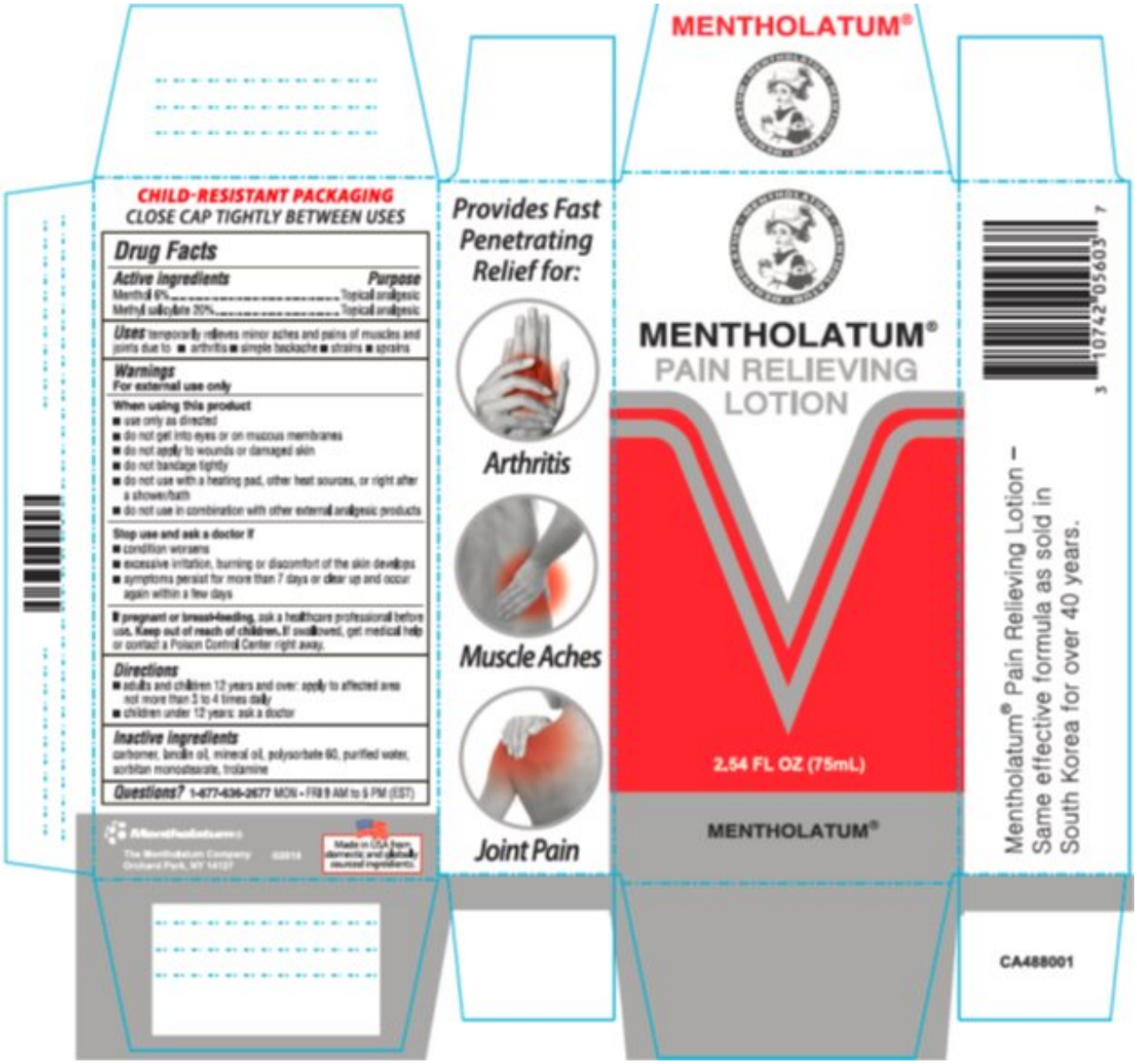
Directions

- adults and children 12 years and over: apply to affected area not more than 3 to 4 times daily
- children under 12 years: ask a doctor

Inactive ingredients

carbomer, lanolin oil, polysorbate 60, purified water, sorbitan monosterate, trolamine

Package/Label Principal Display Panel



MENTHOLATUM PAIN RELIEVING

menthol, methyl salicylate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8169
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	60 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
LANOLIN OIL (UNII: OVV5IIJ58F)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8169-1	1 in 1 CARTON	11/01/2018	
1		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:10742-8169-2	1 in 1 CARTON	11/01/2018	
2		75 mL in 1 BOTTLE; 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	11/01/2018	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8169)

Revised: 2/2023 The Mentholatum Company