

MENTHOLATUM- dl-menthol, methyl salicylate lotion
OASIS TRADING

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.

DL-Menthol, Methyl Salicylate

■ temporary relief aches and pains of muscles and joints associated with:

- arthritis • simple backache
- sprains • strains • bruises

Keep out of reach of children

- Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Warnings

For external use only.

Flammable

■ Keep away from fire, flame, sparks and heated surfaces. Tight cap firmly.

Stop use and ask a doctor if

■ Condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days

When using this product

- Use only as directed
- Avoid contact with eyes
- Do not apply to wounds or damaged skin
- Do not bandage tightly

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children

acetone, chloroxylenol, water

For external use only

MENTHOLATUM

<i>Drug Facts</i>	
<i>Active Ingredients (in 1g)</i>	<i>Purpose</i>
DL-Menthol 60mg -----	Topical analgesic
Methyl Salicylate 200mg -----	Topical analgesic
<i>Uses</i>	
■ temporary relief aches and pains of muscles and joints associated with:	
• arthritis • simple backache	
• sprains • strains • bruises	
<i>Warnings</i>	
For external use only.	
Flammable	
■ Keep away from fire, flame, sparks and heated surfaces. Tight cap firmly.	
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■ Condition worsens or symptoms persist for more than 7days or clear up and occur again within a few days	
When using this product	
■ Use only as direct	
■ Avoid contact with eyes	
■ Do not apply to wounds or damaged skin	
■ Do not bandage tightly	
If pregnant or breast-feeding, ask a health professional before use	
Keep out of reach of children	
<i>Directions</i>	
■ Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily	
■ children under 2 years of age: consult a doctor	
<i>Other Information</i>	
■ Store at room temperature	
<i>Inactive Ingredient</i>	
acetone, chloroxylonol, water	
<i>Questions or comments ?</i>	
Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405	

MENTHOLATUM

dl-menthol, methyl salicylate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72689-0014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RACEMENTHOL (UNII: YS08XHA860) (RACEMENTHOL - UNII:YS08XHA860)	RACEMENTHOL	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
ACETONE (UNII: 1364PS73AF)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72689-0014-1	75 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/15/2018	

Labeler - OASIS TRADING (689991468)**Registrant** - OASIS TRADING (689991468)**Establishment**

Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0014)

Revised: 11/2018

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