

# **MENTHOLATUM DEEP HEATING RUB EXTRA STRENGTH- menthol, methyl salicylate cream**

**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 8%

Methyl salicylate 30%

### **Purpose**

Menthol - External analgesic

Methyl salicylate - External analgesic

### **Uses**

temporarily relieves minor aches and pains of muscles and joints due to

- arthritis
- strains
- simple backache
- 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 damaged skin
- do not bandage tightly
- do not use with 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 2 years and over: apply to affected area not more than 3 to 4 times daily
- children under 2 years: ask a doctor

**Inactive ingredients**

glyceryl stearate, isoceteh-20, poloxamer, purified water, sodium lauryl sulfate, sorbitan monostearate, trolamine

**Questions?**

**1-877-636-2677** MON-FRI 9 AM to 5 PM (EST)

[www.mentholatum.com](http://www.mentholatum.com)

**Package/Label Principal Display Panel**



Principal Display Panel

Arthritis • Joint & Muscle Soreness • Back Pain

ULTRA STRENGTH • FAST ACTING

DEEP HEATING

Pain Relieving Rub

MENTHOLATUM  
- SINCE 1938 -

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Menthol 8% .....	External analgesic
Methyl salicylate 30% .....	External analgesic
<b>Uses</b> temporarily relieves minor aches and pains of muscles and joints due to	
■ arthritis	■ simple backache
■ strains	■ sprains
<b>Warnings</b>	
<b>For external use only</b>	
<b>When using this product</b>	
■ use only as directed	
■ do not get into eyes or on mucous membranes	
■ do not apply to wounds or 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	
<b>Stop use and ask a doctor if</b>	
■ 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	

**Drug Facts (continued)**

**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** glyceryl stearate, isoceteth-20, poloxamer, purified water, sodium lauryl sulfate, sorbitan monostearate, trolamine

**Questions?**  
1-877-636-2677 MON-FRI 9 AM to 5 PM (EST)  
www.mentholatum.com

Manufactured by:  
The Mentholatum Company  
Orchard Park, NY 14127 USA

©2020 CA280006  
 Mentholatum®

<b>MENTHOLATUM DEEP HEATING RUB EXTRA STRENGTH</b>			
menthol, methyl salicylate cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-2002
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	80 mg in 1 g
	<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	300 mg in 1 g
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>	<b>Strength</b>	
	<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)		
	<b>ISOCETETH-20</b> (UNII: O020065R7Z)		
	<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)		
	<b>WATER</b> (UNII: 059QF0KO0R)		
	<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)		
	<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ410H58X)		
	<b>TROLAMINE</b> (UNII: 903K93S3TK)		

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-2002-4	2 in 1 CARTON	12/15/1992	
1		57 g in 1 TUBE; 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	12/15/1992	

**Labeler** - The Mentholatum Company (002105757)

**Registrant** - The Mentholatum Company (002105757)

## Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-2002)

Revised: 2/2023

The Mentholatum Company