

## **SOOTHE- menthol cream**

### **Clay Therapy**

*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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Purified water, Glycerin, Mentha Arvensis Leaf Essential Oil, Helianthus Annuus (Sunflower) Seed Oil, Arnica Montana Flower Extract, Canadian Colloidal Clay, Sodium Carbomer, Caprylyl Glycol, Phenoxyethanol, Citrus Limon (Lemon) Peel Essential Oil, Rosmarinus Officinalis (Rosemary) Leaf Essential Oil, Eucalyptus Globulus Leaf Essential Oil, Gaultheria Procumbens (Wintergreen) Leaf Oil, Pine (Pinus sylvestris) Essential Oil, Cinnamomum Camphora (Camphor) Bark Essential Oil, Polysorbate 80

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

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 physician.

Menthol 2.5%

Topical Analgesic

For external use only. Use only as directed.

Stop use and ask 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 - Avoid contact with eyes - Do not apply to wounds or damaged skin - Do not bandage tightly

Flammable - Keep away from fire or flame.

If pregnant or breastfeeding, ask a health care professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

For the temporary relief of minor aches and pains of muscles and joints.



# SOOTHE

Naturally Sourced  
Pain Relieving Cream



60 mL / 2 fl oz

Drug Facts	
<b>Active Ingredient</b> Menthol 2.5%	<b>Purpose</b> Topical Analgesic
<b>Uses</b> For the temporary relief of minor aches and pains of muscles and joints.	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>■ For external use only. Use only as directed.</li> <li>■ Stop use and ask doctor if - Condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days</li> <li>■ When using this product - Avoid contact with eyes - Do not apply to wounds or damaged skin - Do not bandage tightly</li> <li>■ Flammable - Keep away from fire or flame.</li> <li>■ If pregnant or breast-feeding, ask a health care professional before use.</li> <li>■ Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ Adults and children 2 years of age and older. Apply to affected area not more than 3 to 4 times daily.</li> <li>■ Children under 2 years of age: consult a physician.</li> </ul>	
<b>Other Information</b> Store at 15 to 30°C (59 to 86°F). Close cap tightly after use.	
<b>Inactive ingredients</b> Purified Water, Glycerin, Mentha Arvensis Leaf Essential Oil, Helianthus Annuus (Sunflower) Seed Oil, Arnica Montana Flower Extract, Canadian Colloidal Clay, Sodium Carbomer, Caprylyl Glycol, Phenylethanol, Citrus Limon (Lemon) Peel Essential Oil, Rosmarinus Officinalis (Rosemary) Leaf Essential Oil, Eucalyptus Globulus Leaf Essential Oil, Gaultheria Procumbens (Wintergreen) Leaf Oil, Pine (Pinus sylvestris) Essential Oil, Cinnamomum Camphora (Camphor) Bark Essential Oil, Polysorbate 80	



Any questions call 250-575-3890.

Distributed by Clay Therapy  
3151 Lakeshore Road, Suite 2749  
Kelowna, BC, V1W 3S9

claytherapy.co



## SOOTHE

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81771-7001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	25 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PINUS SYLVESTRIS WHOLE</b> (UNII: VP00HZL9IC)	
<b>ARNICA MONTANA FLOWER WATER</b> (UNII: U7L2JP51PR)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CITRUS LIMON FRUIT OIL</b> (UNII: 0HNC1J1YED)	
<b>GAULTHERIA PROCUMBENS LEAF</b> (UNII: 2125M16OWN)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6)	

<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CINNAMOMUM CAMPHORA LEAFY TWIG</b> (UNII: 6RGO3JFT61)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ROSMARINUS OFFICINALIS FLOWERING TOP OIL</b> (UNII: OXN0D3N28L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHA ARVENSIS LEAF OIL</b> (UNII: 1AEY1M553N)	
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81771-7001-1	60 mL in 1 TUBE; Type 0: Not a Combination Product	05/19/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/19/2021	

**Labeler** - Clay Therapy (204269414)

**Registrant** - Clay Therapy (204269414)