

HOT STUFF- menthol, methyl salicylate cream
Mueller Sports Medicine

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.

Active Ingredients

Active Ingredients

Menthol 3%

Methyl Salicylate 15%

Purpose

Purpose

Topical Analgesic

Topical Analgesic

Uses

Temporarily relieves pain from

- sore muscles
- minor aches
- sprains
- strains
- bruises

For external use only

Allergy alert: If prone to allergic reaction from **menthol**, aspirin or salicylates, consult a doctor before use.

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with a heating pad
- do not use immediately after a shower or bath

Stop use and ask a doctor

Stop use and ask a doctor if condition worsens

- symptoms persist for more than 7 days or clear up and occur again within a few days
- skin redness is present
- excessive skin irritation occurs

If pregnant or breast-feeding

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

Keep out of reach of children

Keep out of children

- if swallowed, get medical help or contact a Poison Control center right away

Directions

Adults and children 12 years of age and over: apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: ask a doctor

Inactive ingredients

Cetyl Alcohol, Cetyl Palmitate, Glyceryl Stearate, Methyl Paraben, Mineral Oil, Polysorbate 80, Propylene Glycol, Propyl Paraben, Water

Questions or comments?

Call 1-800-356-9522 or

Email us at sportcare@muellersportsmed.com

STORE AT NORMAL ROOM TEMPERATURE



**PAIN
RELIEVING
SPORTS CREAM**

- SORE MUSCLES**
- ARTHRITIS PAIN**
- BODY ACHES**

**HOT
STIFF**

Mueller
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Drug Facts	
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Methyl Salicylate 15%	Topical Analgesic
Uses Temporarily relieves pain from ■ sore muscles ■ minor aches ■ sprains ■ strains ■ bruises	
Warnings For external use only. Allergy alert: If prone to allergic reaction from menthol, aspirin or salicylates, consult a doctor before use. When using the product ■ use only as directed ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin ■ do not bandage tightly ■ do not use with a heating pad ■ do not use immediately after a shower or bath Stop use and ask a doctor if condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ skin redness is present ■ excessive skin irritation occurs If pregnant or breast-feeding, ask a health professional before using Keep out of reach of children. ■ If swallowed, get medical help or contact a Poison Control center right away	
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39400
LBL39400 - 12.17



NET WT 8 FL OZ (237 mL)



HOT STUFF

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52564-108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.15 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52564-108-01	237 g in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2019	

Labeler - Mueller Sports Medicine (006426316)

Revised: 4/2019

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