

ROCK SAUCE - methyl salicylate, menthol, capsicum lotion
Shine & Pretty (USA), Corp.

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.

Uses: Temporarily relieves minor muscular discomfort

When using this product, do not: heat, microwave, add to hot water or any container where heating water may cause splattering and result in burns, use in eyes or directly on mucous membrane, take by mouth or place in nostrils, apply to wounds or damaged skin.

Warnings: For external use only. Avoid contact with eyes. Ask a doctor before use if you have a cough associated with smoking, excessive phlegm, asthma, emphysema, persistent or chronic cough.

Directions: For the temporary relief of minor muscular discomfort. See important warnings under "When using this product". Not for use on children 5 years or younger. Apply liberally to painful area and massage until lotion is absorbed into the skin. Repeat 3-4 times daily.

Inactive Ingredients: D. I. Water, Ethylhexyl Palmitate, Cetearyl Alcohol, Glycerin, Propylene Glycol, Arnica Extract, Aloe Barbadensis (Aloe Vera) Leaf Extract, Vitamin E Acetate, Carbomer, Triethanolamine, Phenoxyethanol and Methylidibromide Glutaronitrile

Keep out of the reach of children: In case of accidental ingestions, get medical help or call Poison Control Center right away.

Active Ingredient

Methyl Salicylate 20%

Menthol 10%

Capsicum 0.05%

Consult a doctor and discontinue use: If conditions persist for more than 1 week or reoccur.



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ROCK SAUCE

methyl salicylate, menthol, capsicum lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59663-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	20 mL in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mL in 100 mL
CAPSIUM (UNII: 00UK7646FG) (CAPSIUM - UNII:00UK7646FG)	CAPSIUM	0.05 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARNICA MONTANA (UNII: O80TY208ZW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER 934 (UNII: Z135WT9208)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLDIBROMO GLUTARONITRILE (UNII: YX089CPS05)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59663-100-01	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/13/2012	

Labeler - Shine & Pretty (USA), Corp. (603528605)

Revised: 6/2011

Shine & Pretty (USA), Corp.