PAIN RELIEF RUB IAMPUR- camphor, menthol, methyl salicylate cream Avaria Health & Beauty 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.

Avaria Pain Relief Rub

Camphor 4%, Menthol 4%, Methyl Salicylate 11%

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, back ache, strains, bruises, and sprains.

Warnings

For external use only. Use only as directed. Consult your doctor before use if you have allergies to aspirin or salicylate. Avoid contact with eyes and mucous membranes. If contact occurs, flush with water for 15 minutes. Do not apply to wounds or damaged skin. If pain persists for more than 7 days or becomes worse consult a physician. Children under 12 years of age should consult a physician before use.

Directions

Adults and children 12 years of age and older: use no more than 3 to 4 times daily. Apply cream to affected areas and thoroughly massage until penetrated. Wash hands with soap and water after use.

Inactive ingredients

Arnica Montana, Carbomer, Cetearyl Alcohol, Ceteth-10 Phosphate, Dicetyl Phosphate, Glycerin, Isopropyl Palmitate, Methylsulfonylmethane (MSM), Oryza sativa (Rice) Bran Oil, Phenoxyethanol, Purified Water, Sodium Hydroxide

Purpose

Topical Analgesic.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

NDC 434930001

AVARIA

PAIN RELIEVING RUB

with Arnica

DRUG FACTS:

Active Ingredients Purpose

Methyl Salicylate 1196 Camphor 496 Menthol 496 Topical Analgesic Topical Analgesic Topical Analgesic

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Penetrating pain rub for the temporary relief of minor muscle and joint pain associated with arthritis, backache, strains, sprains and bruises.

Warnings

For external use only. Use only as directed, Consult your doctor before use if you have allergies to aspirin or salicylate. Avoid contact with eyes and mucous membranes. If contact occurs, flush with water for 15 minutes. Do not apply to wounds or damaged skin. If pain persists for more than 7 days or becomes worse consult a physician. Children under 12 years of age should consult a physician before use. KEEP OUT OF REACH OF CHILDREN.

Directions

Adults and children 12 years and over.

Store at 59°F - 77°F,

Use no more than 3-4 times daily. Apply cream to affected areas and thoroughly massage until penetrated. Wash hands with soap and water after use.

Inactive Ingredients

Arnica Montana, Carborner, Cetearyl Alcohol, Ceteth-10 Phosphate, Dicetyl Phosphate, Glycerin, Isopropyl Palmitate, Methylsulfonylmethane (MSM), Oryza sativa (Rice) Bran Oil, Phenoxyethanol, Purified Water, Sodium Hydroxide

A Synergistic Blend of Science & Nature

Avaria Health & Beauty Corp.

330 Carswell Ave Holly Hill, FL 32117





PAIN RELIEF RUB IAMPUR

camphor, menthol, methyl salicylate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:43493-0001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	4 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	11 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)		
DIHEXADECYL PHO SPHATE (UNII: 2V6E5WN99N)		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
WATER (UNII: 059QF0KO0R)		
ARNICA MONTANA (UNII: O80TY208ZW)		
RICE BRAN O IL (UNII: LZO6K1506A)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3 M)		

I	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43493-0001-1	198 g in 1 TUBE; Type 0: Not a Combination Product	10/30/2017	
2	NDC:43493-0001-2	56 g in 1 TUBE; Type 0: Not a Combination Product	10/30/2017	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	10/30/2017			

Labeler - Avaria Health & Beauty Corp (248926979)

Establishment					
Name	Address	ID/FEI	Business Operations		
Product Quest Mfg, LLC		927768135	manufacture (43493-0001)		

Revised: 11/2017 Avaria Health & Beauty Corp