

MOBISYL- trolamine salicylate cream
BF ASCHER AND CO INC

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.

Mobisyl

Active ingredientPurpose

Trolamine salicylate 10%.....Topical analgesic

Use

For temporarily relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, lumbago, neuralgia, strains, bruises, and sprains

Use

Temporarily relieves minor aches and pains of muscles and joints associated with arthritis, simple backache, lumbago, neuralgia, strains, bruises, and sprains.

Warnings

For external use only.

Use only as directed

Do not use

- on or near the eyes
- on broken, damaged, or irritated skin

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Keep this and all drugs out of reach of children. In case of ingestion, get medical help or contact a poison control center immediately.

Directions

- adults and children 12 years and older: massage a liberal amount into the affected area three or four times a day, especially before retiring
- children under 12 years of age: consult your doctor

Other information

- store tightly capped at 59°- 86° F (15°- 30° C)
- mfd. in the USA for B.F. Ascher & Co., Inc.

Inactive ingredients: allantoin, aloe vera gel, carbomer, cetyl alcohol, citric acid, diazolidinyl urea, glycerin, glyceryl stearate, iodopropynyl butylcarbamate, isopropyl palmitate, lecithin, mineral oil, potassium sorbate, propylene glycol, sodium benzoate, sodium dehydroacetate, sodium hydroxide, sodium sulfite, stearic acid, sweet almond oil, tetrasodium EDTA, and water

Questions? Call 1-800-324-1880, 7:30am - 4:00pm Central, M - F, or visit

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0225-0360
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TROLAMINE SALICYLATE (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	TROLAMINE SALICYLATE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALMOND OIL (UNII: 66YXD4DKO9)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
ALLANTOIN (UNII: 344S277G0Z)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE (UNII: V5VD430YW9)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0225-0360-35	226.8 g in 1 JAR; Type 0: Not a Combination Product	09/19/2014	
2	NDC:0225-0360-11	100 g in 1 TUBE; Type 0: Not a Combination Product	09/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not			

OTC monograph not
final

part348

09/19/2014

Labeler - BF ASCHER AND CO INC (003854403)

Revised: 11/2022

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