

BUMOOLY-S - methyl salicylate solution
Scott Holdings Co., Ltd.

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.

Drug Facts

methyl salicylate

camphor, menthol, glycyrrhetic acid, diphenhydramine hcl, dibucaine hcl

eczema, dermatitis, erosion, miliaria, pruritus, pernio, insect bite, hives

keep out or reach of the children

apply to the affected area once to several times a day

avoid contact with eyes, if this product splashes in to your eyes, wash immediately with water

for external use only



BUMOOLY-S

methyl salicylate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68994-4001
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)		METHYL SALICYLATE	3 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
MENTHOL (UNII: L7T10EP3A)				
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)				
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)				
DIBUCAINE HYDROCHLORIDE (UNII: Z97702A5DG)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68994-4001-1	50 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part348	09/25/2014		

Labeler - Scott Holdings Co., Ltd. (689665651)

Registrant - Scott Holdings Co., Ltd. (689665651)

Establishment

Name	Address	ID/FEI	Business Operations
Hyundai Pharmaceutical Co., Ltd.		687874958	manufacture(68994-4001)

Revised: 5/2014

Scott Holdings Co., Ltd.