

ALA-SEPTIC- salicylic acid cream
Ala-Septic Pharmaceutical Research LLC

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.

Ala-Septic

warnings

For external use only.

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Do not use without consulting a doctor if the condition appears over a large portion of the body.

If condition worsens, or does not improve after using as directed, consult physician.

Do not use for prolonged periods without consulting a doctor.

Active ingredient

Salicylic Acid 2.00%

Purpose

Dermatitis Treatment

Use for:

For relief of itching, irritation, redness and scaling associated with psoriasis, eczema and seborrheic dermatitis.

Other ingredients:

Aloe Barbadosensis Leaf Juice, Aqua (deionized water), benzoic acid, butylene glycol, C13-14 isoparaffin, ethylhexylglycerin, glycyrrhiza glabra (licorice) extract, iodoquinol, isopropyl myristate, larrea tridentata extract, larueth-7, melaleuca alternifolia (tea tree) oil, phenoxyethanol, polyacrylamide, polysorbate-20, SD-alcohol 40B, tocopheryl acetate (vitamin E).

Keep out of reach of children.

If swallowed, contact physician or poison control center immediately.

Directions:

Wash affected areas well with soap and water. Pat dry. Apply cream to affected area one to four times per day, or as directed by physician.



ALA-SEPTIC

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59434-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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ALOE VERA WHOLE (UNII: KIZ4X2EHYX)
water (UNII: 059QF0KO0R)
BENZOIC ACID (UNII: 8SKN0B0MM)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
LICORICE (UNII: 61ZBX54883)
IODOQUINOL (UNII: 63W7IE88K8)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
LARREA TRIDENTATA WHOLE (UNII: B755J144H1)
LAURETH-7 (UNII: Z95S6G8201)
TEA TREE OIL (UNII: VIF565UC2G)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
ALCOHOL (UNII: 3K9958V90M)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59434-001-04	100 g in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	10/01/2013	

Labeler - Ala-Septic Pharmaceutical Research LLC (964652692)

Establishment			
Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(59434-001)