BHA CLEANSER 2%- salicylic acid lotion Skinfix, 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.

SKINFIX - ACNE+ 2% BHA CLEANSER

Active Ingredient

SALICYLIC ACID 2%

Purpose

ACNE TREATMENT

USES

HELPS CLEAR ACNE BLEMISHES AND ALLOWS SKIN TO HEAL. HELPS KEEP SKIN CLEAR OF NEW ACNE BLEMISHES. HELPS PREVENT NEW ACNE BLEMISHES FROM FORMING.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

 SKIN IRRITATION AND DRYNESS IS MORE LIKELY TO OCCUR IF YOU USE ANOTHER TOPICAL ACNE MEDICATION AT THE SAME TIME. IF IRRITATION OCCURS, ONLY USE ONE TOPICAL ACNE MEDICATION AT A TIME.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away

Directions

DISPENSE A PEA-SIZED AMOUNT ONTO DAMP PALMS AND WORK INTO A LATHER.
MASSAGE OVER FACE AND NECK IN AN OUTWARD, CIRCULAR MOTIONS,
CONCENTRATING ON OILY AND BREAKOUT-PRONE AREAS. RINSE THOROUGHLY WITH WARM WATER.

ALLERGY ALERT DO NOT USE THIS PRODUCT IF YOU HAVE A KNOWN ALLERGY TO SALICYLIC ACID.

Inactive Ingredients

WATER (EAU), COCAMIDOPROPYL HYDROXYSULTAINE, STEARYL ALCOHOL, PROPANEDIOL, DISODIUM COCOYL GLUTAMATE, GLYCOLIC ACID, BENTONITE,

NIACINAMIDE, SODIUM HYDROXIDE, AZELAIC ACID, CAMELLIA SINENSIS LEAF EXTRACT, TOCOPHEROL, GLYCERIN, ETHYLHEXYLGLYCERIN, POLYDEXTROSE, DEXTRIN, AMYLOPECTIN, SODIUM COCOYL GLUTAMATE, XANTHAN GUM, SODIUM CHLORIDE, CITRIC ACID, POTASSIUM SORBATE, PHENOXYETHANOL, SODIUM BENZOATE

QUESTIONS?

1.866.927.2783





salicylic acid lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61328-403

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PROPANEDIOL (UNII: 5965N8W85T)	
DISODIUM COCOYL GLUTAMATE (UNII: MBK0CP8F5A)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
BENTONITE (UNII: A3N5ZCN45C)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
AZELAIC ACID (UNII: F2VW3D43YT)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
AMYLOPECTIN, UNSPECIFIED SOURCE (UNII: 4XO4QFV777)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:61328-403- 55	1 in 1 BOX	02/04/2022			
1	NDC:61328-403- 15	148 mL in 1 TUBE; Type 0: Not a Combination Product				
2	NDC:61328-403- 01	30 mL in 1 TUBE; Type 0: Not a Combination Product	02/04/2022			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333D	02/04/2022				
3 7						

Labeler - Skinfix, Inc. (203158183)

Registrant - Skinfix, Inc. (203158183)

Establishment							
Name	Address	ID/FEI	Business Operations				
SIGAN INDUSTRIES INC		255106239	manufacture(61328-403)				

Revised: 2/2022 Skinfix, Inc.