

BIOARPIL - salicylic acid ointment
BIOARPIL USA, 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.

Drug Facts

Active Ingredient

Salicylic Acid 2%

Purpose:

psoriasis and seborrheic dermatitis

Keep out of reach of children. If swallowed, get immediate medical help or contact a Poison Control Center immediately.

Uses relieves and helps prevent recurrence of skin itching, irritation, redness, flaking, scaling due to psoriasis and seborrheic dermatitis

Warnings

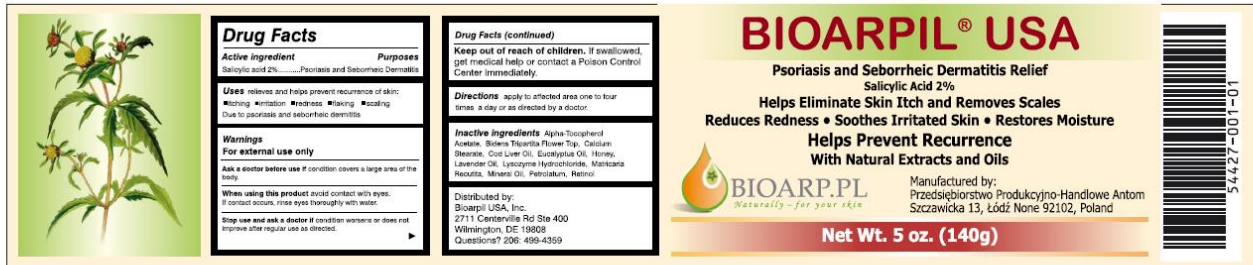
- For external use only
- Ask a doctor before use if condition covers a large part of the body
- When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water
- Stop use and ask a doctor if condition worsens or does not improve after regular use as directed

Directions

Apply to affected area one to four times daily or as directed by a doctor

Inactive Ingredients

Alpha-Tocopherol Acetate, Bidens Tripartita Flower Top, Calcium Stearate, Cod Liver Oil, Eucalyptus Oil, Honey, Lavender Oil, Lysozyme Hydrochloride, Matricaria Recutita, Mineral Oil, Petrolatum, Retinol.



BIOARPIL
salicylic acid ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54427-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2.8 g in 140 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BIDENS TRIPARTITA FLOWERING TOP (UNII: 7378E9Z0AL)	
CALCIUM STEARATE (UNII: 776XM7047L)	
COD LIVER OIL (UNII: BBL281NWFQ)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
HONEY (UNII: Y9H1V576FH)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LYSOZYME HYDROCHLORIDE (UNII: 4YRW73H69V)	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
RETINOL (UNII: G2SH0XKK91)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54427-001-01	1 in 1 BOX		
1		140 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	07/01/2012	

Labeler - BIOARPIL USA, INC. (078675445)

Establishment

Name	Address	ID/FEI	Business Operations
PRZEDSIĘBIORSTWO PRODUKCJI I HANDLOWE AN TOM		366004067	manufacture(54427-001)

Revised: 12/2012

BIOARPIL USA, INC.