

PSORACARE - salicylic acid cream
Healingsmith Institute 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.

Salicylic Acid 2%

Psoriasis, Seborrheic Dermatitis

controls, fights, and helps prevent skin itching, irritation, redness, flaking and scaling associated with:

- psoriasis
- seborrheic dermatitis

For external use only.

Do not use if you are allergic to sesame oil.

Ask a doctor before use if condition covers a large area of the body.

When using this product

- avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water
- if you currently use steroids or have used steroids in the recent past, it may take 1 to 3 months to see results

Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed.






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

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

- apply liberally to affected areas one to four times daily or as directed by a doctor
- children under 2 years of age: consult a doctor

store in a cool and dry place

Beeswax, Carbomer, Cetyl Alcohol, Coccinia Indica fruit extract, EDTA, Fragrance, Glyceryl Stearate, Holarrhena Antidysenterica leaf extract, Melia Azadirachta leaf extract, Propylene Glycol, Sesamum Indicum (Sesame) seed oil, Sodium Lauryl Sulfate, Sodium Methylparaben, Sodium Propylparaben, Stearic Acid, Triethanolamine, Polysorbate 60, White soft paraffin

		Psoriasis Cream					
Made with Soothing Plant Extracts							
 <p>Salicylic Acid 2%</p>							
Psoriasis Cream							
<ul style="list-style-type: none"> Fights irritated, itching and flaking skin associated with psoriasis Does not contain steroids Inspired by Ayurvedic principles 		<p>For hundreds of years, people have used plant extracts and natural ingredients in ancient traditions such as Ayurveda.</p> <p>Healingsmith's PsoraCare Cream maximizes the use of plant extracts and botanicals to deliver outstanding results. It contains Salicylic Acid and soothing herbs to fight irritated, itching and flaking skin due to Psoriasis and Seborrheic Dermatitis. It was developed by Sankunni Ayurvedic Foundation which is based in India. Sankunni was established in 1910.</p>					
 <p>Net wt 2 oz (56.7g)</p>		 <p>Psoriasis Cream</p> <p>www.healingsmith.com</p>					
		<p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredients</td> <td>Purpose</td> </tr> <tr> <td>Salicylic Acid 2%</td> <td>Psoriasis Seborrheic Dermatitis</td> </tr> </table> <p><i>Uses</i> controls, fights, and helps prevent skin itching, irritation, redness, flaking and scaling associated with: • psoriasis • seborrheic dermatitis</p> <p>Warnings For external use only. Do not use if you are allergic to sesame oil. Ask a doctor before use if condition covers a large area of the body. When using this product • avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water • if you currently use steroids or have used steroids in the recent past, it may take 1 to 3 months to see results Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed. If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions • apply liberally to affected areas one to four times daily or as directed by a doctor • children under 2 years of age: consult a doctor</p> <p>Other Information • store in a cool and dry place</p> <p>Inactive Ingredients Beeswax, Carbomer, Cetyl Alcohol, Coccinia Indica fruit extract, EDTA, Fragrance, Glyceryl Stearate, Holarrhena Antidysenterica leaf extract, Melia Azadirachta leaf extract, Propylene Glycol, Sesamum Indicum (Sesame) seed oil, Sodium Lauryl Sulfate, Sodium Methylparaben, Sodium Propylparaben, Stearic Acid, Triethanolamine, Polysorbate 60, White soft paraffin</p> <p>Keep carton. It contains important Warnings Information.</p> <p>Lot No: _____ Exp Date: _____</p> <p>Distributed by: Healingsmith Institute Inc. 12460 Crabapple Road, Ste 202-255 Alpharetta GA 30004 Made in India</p>		Active Ingredients	Purpose	Salicylic Acid 2%	Psoriasis Seborrheic Dermatitis
Active Ingredients	Purpose						
Salicylic Acid 2%	Psoriasis Seborrheic Dermatitis						
		<p>Healingsmith's PsoraCare Cream uses powerful herbs and oils to soothe the skin and most people will start seeing results in just 1 to 2 weeks.</p> <p>The formula is non-greasy and gets absorbed into the skin quickly. For best results, we recommend that you apply the cream at least twice a day.</p>					
		 <p>Psoriasis Cream</p> <p>www.healingsmith.com</p>					

PSORACARE

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76066-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1.1 g in 56.7 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)	
EDETIC ACID (UNII: 9G34HU7RV0)	
HOLARRHENA PUBESCENS BARK (UNII: 5R6HPB294Y)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SESAME OIL (UNII: QX10HYY4QV)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76066-002-02	56.7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/02/2012	

Labeler - Healingsmith Institute Inc. (962842642)

Registrant - Healingsmith Institute Inc. (962842642)

Establishment

Name	Address	ID/FEI	Business Operations
Nikita Containers Private Limited		862345246	manufacture

Revised: 11/2011

Healingsmith Institute Inc.