

ACNE- salicylic acid cream
GREENBRIER INTERNATIONAL 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 0.5%

Purpose

Acne Treatment

Uses

for the treatment of acne

Warnings

For external use only.

Do not use if you have very sensitive skin or are sensitive to Salicylic Acid

Ask a doctor or pharmacist before use if you are using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

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

Directions

Cleanse the skin thoroughly before applying medication. Apply cream directly on acne pimples. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day.

Other information

store at 20 to 25 C (66 to 77 F)

Inactive ingredients

carbomer, cetyl alcohol, dimethicone, glycerin, glycol stearate, methylparaben, propylene glycol, propylparaben, squalane, triethanolamine, water



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ACNE		
salicylic acid cream		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:33992-1307
Route of Administration	TOPICAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	14 g in 100 g
Inactive Ingredients		
Ingredient Name	Strength	

DIMETHICONE (UNII: 92RU3N3Y1O)

2 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-1307-1	1 in 1 BOX		
1		43 g in 1 TUBE		

Marketing Information

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

Labeler - GREENBRIER INTERNATIONAL INC (610322518)

Registrant - HUZHOU MINO DAILY CHEMICALS COMPANY LIMITED (547695235)

Establishment

Name	Address	ID/FEI	Business Operations
HUZHOU MINO DAILY CHEMICALS COMPANY LIMITED		547695235	manufacture(33992-1307)

Revised: 7/2014

GREENBRIER INTERNATIONAL INC