

ADVANCED ACNE SPOT TREATMENT - salicylic acid gel
Shanghai Weierya Daily Chemicals Factory

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

Acne treatment

Uses for the treatment of acne

Warnings

For external use only.

Flammable. Keep away from fire or flame.

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

When using this product apply to affected area only. Do not use on broken skin or apply to large areas of the body.

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

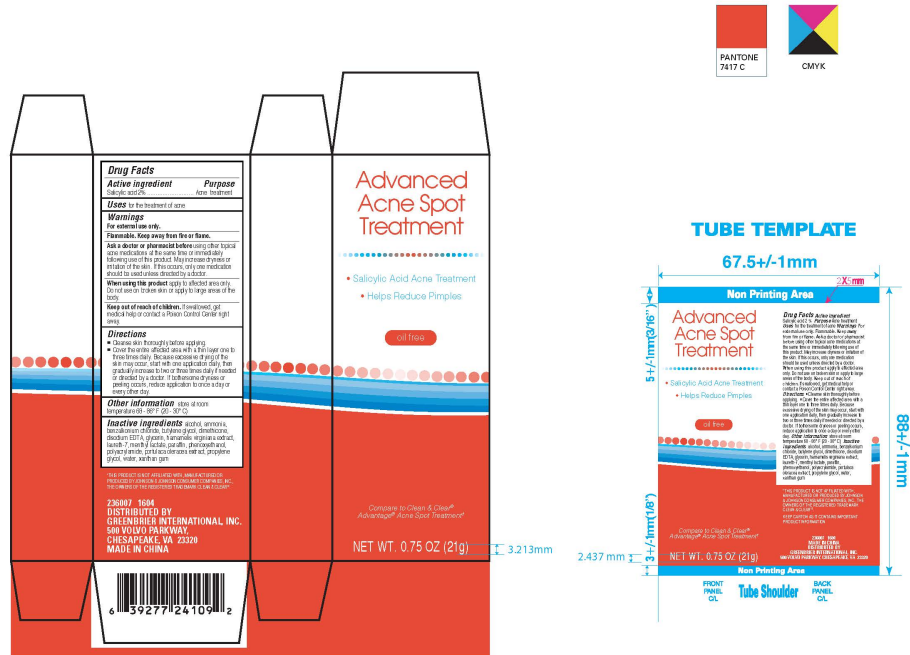
Directions

-Cleanse skin thoroughly before applying.
-Cover the entire affected area with a thin layer one to three times daily. 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 directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Other information store at room temperature 68 - 86 F (20 - 30 C)

Inactive ingredients alcohol, ammonia,

benzalkonium chloride, butylene glycol, dimethicone, disodium EDTA, glycerin, hamamelis virginiana extract, laureth-7, menthyl lactate, paraffin, phenoxyethanol, polyacrylamide, portulaca oleracea extract, propylene glycol, water, xanthan gum



ADVANCED ACNE SPOT TREATMENT

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 194-030
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
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIMETHICONE (UNII: 92RU3N3Y1O)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)
LAURETH-7 (UNII: Z95S6G8201)
METHYL LACTATE, (-)- (UNII: 0379G9C44S)
PARAFFIN (UNII: I9O0E3H2ZE)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYACRYLAMIDE (1300000 MW) (UNII: SC5Y4X78TG)
PURSLANE (UNII: M6S840WYG5)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
WATER (UNII: 059QF0K00R)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 194-030-01	1 in 1 CARTON		
1		21 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/11/2016	

Labeler - Shanghai Weierya Daily Chemicals Factory (420359333)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Weierya Daily Chemicals Factory		420359333	manufacture(58 194-030)

Revised: 1/2016

Shanghai Weierya Daily Chemicals Factory