ADVANCE ACNE CARE- salicylic acid, silver Swabplus 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.

Advance Acne Care Swab

Drug Facts
Active Ingredients
Advance Acne Care Swabs step 1
Silver 0.001%

Advance Acne Care Swabs Step 2

Salicylic Acid 2.0%

Purpose

For skin acne medication

Uses

When using this product. Avoid contact with eyes. If contact occures, flush throughly with water. Using other topical acne medications at teh same time or immediately following use this product may increase dryness or irritation of the skin. If this occures, only one medication should be used unless directed by a doctor. Do not insert in teh canal.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Do not use if label seal is broken prior to purchase. Keep swabs in original container when not in use. Treatment Swabs have a red color band.
- Use Cleansinh swab to cleanse the skin throughly before applying medication.
- Hold the swab vertically, with the color ring band tip upwards.
- Bend the tip at the color band to one side until it snaps. Medicine will flow to theother end.
- Cover the entire affected area with a thin layer 1 to 3 times daily. Discard swab after use.
- Each swab can be used on multipe pimples.
- Because excesssive drying of the skin may occur start with 1 application daiky then gradually increase to 2 or 3 times daily if needed, or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every othr day.

Warnings

For external use only.

Other information

Avoid storing at excessive heat.

Inactive Ingredients

Allantoin, Aloe Vera leaf Juice, Diazolidinyl Urea, Isoceteth-20, Methyl Gluceth-20, Methylparaben, Propylene Glycol, Propylparaben, Red 33, Red 40, Sodium Hydroxide, Sodium PCA, Sorbitol, Tetrasodium EDTA, Water, Witch Hazel.

Water, Sodium Lauryl Sulfate, Citric Acid, Silver.

Package carton

Image of Acne Care Carton



ADVANCE ACNE CARE

salicylic acid, silver kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65734-740

ŀ	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:65734-740-00	1 in 1 CARTON				

Quan	Quantity of Parts				
Part # Package Quantity		Total Product Quantity			
Part 1	13 APPLICATOR	2 mL			
Part 2	13 APPLICATOR	2 mL			

Part 1 of 2

ACNE CARE SWAB STEP 1 CLEAN

silver solution

Product Information	
Item Code (Source)	NDC:65734-741
Route of Administration	TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SILVER (UNII: 3M4G523W1G) (SILVER - UNII:3M4G523W1G)	SILVER	0.1 mg in 10 mL		

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
CITRIC ACID ACETATE (UNII: DSO 12WL7AU)			
WATER (UNII: 059QF0KO0R)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:65734-741-24	24 in 1 PACKAGE			
1 NDC:65734-741-00	0.15 mL in 1 APPLICATOR			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		08/07/2008			

Part 2 of 2

ACNE CARE SWAB STEP 2 TREAT

salicylic acid solution

Product Information

Item Code (Source) NDC:65734-742

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALLANTO IN (UNII: 344S277G0Z)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
ISOCETETH-20 (UNII: O020065R7Z)			
METHYL GLUCETH-20 (UNII: J3QD0LD11P)			
METHYLPARABEN (UNII: A218 C7HI9 T)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
SODIUM (UNII: 9NEZ333N27)			
SORBITAN (UNII: 6O92ICV9RU)			
WATER (UNII: 059QF0KO0R)			
WITCH HAZEL (UNII: 10 114J0 U34)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65734-742-24	24 in 1 PACKAGE			
1	NDC:65734-742-00	0.15 mL in 1 APPLICATOR			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	08/07/2008		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	08/07/2008		

Labeler - Swabplus Inc. (876441549)

Registrant - Swabplus Inc. (876441549)

Establishment			
Name	Address	ID/FEI	Business Operations
Swabplus Inc.		876441549	repack(65734-740), manufacture(65734-741, 65734-742)

Revised: 3/2015 Swabplus Inc.