SKIN PHARMACY ADVANCED ACNE THERAPY OVERNIGHT SALICYLIC ACID- salicylic acid liquid

AMCOL Health & Beauty Solutions, Inc. DBA

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.

SKIN+PHARMACY ADVANCED ACNE THERAPY OVERNIGHT SALICYLIC ACID LOTION

HBS Code (Labeler): FP40901-30.2

Distributor: CVS Pharmacy, Inc.

Human OTC Drug

Active Ingredients: Salicylic Acid 2%

CARTON TEXT

SKIN+PHARMACY

ADVANCED ACNE THERAPY

OVERNIGHT SALICYLIC ACID LOTION with Microsponge® Technology

Maximum Strength 2% Salicylic Acid

- works overnight to help eliminate existing blemishes
- helps prevent new breakouts from forming
- contains anti-inflammatory Bisabolol & soothing Ale Vera to calm skin
- fragrance- & oil-free formula

DERMATOLOGIST TESTED

exclusively at CVS/pharmacy

Actual Size Product on Side Panel

1 FL OZ (30 mL)

The advanced Overnight Salicylic Acid Lotion is formulated with Microsponge® technology, which is specially designed to promote healthy, visibly clear skin. This sustained-release acne-fighting technology helps reduce irritation by continuously working overnight, providing efficacy as it gently soothes and moisturizes skin, without clogging pores. Maximum strength salicylic acid exfoliates as it works to help clear existing acne and prevent new breakouts from forming. This unique formula contains anti-inflammatory Bisabolol, and Aloe Vera to help soothe, calm and condition skin.

Key Benefits:

- helps eliminate existing blemishes
- helps prevent new breakouts from forming
- soothing, oil-free formula
- unclogs pores
- fragrance free

Daily Regiment:

For best results, use this product with the full Skin+Pharmacy Advanced Acne Therapy regimen.

1. Cleanse

Clarifying Daily Cleanser Gentle Exfoliating Scrub

2. Moisturize

Active Clearing Lotion

3. Treat

Spot Treatment
Targeted Treatment Wipes
Overnight Salicylic Acid Lotion
Mattifying Lotion

Warning: This product contains a chemical known to the State of California to cause cancer.

Skin+Pharmacy Advanced Acne Therapy is an innovative line of clinically tested skin care products that help reduce the appearance of acne. These products, exclusive to CVS/pharmacy, are less irritating to skin, yet powerful enough to treat breakouts and unclog pores. Let Skin+Pharmacy help improve your appearance toward a clear, acne-free complexion.

Actual Size

Drug Facts

Active Ingredient

Salicylic Acid 2%

Purpose

Acne treatment

Use

for the management of acne

Warnings

For external use only

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid contact with eves. If contact occurs, flush thoroughly with water

Keep out of reach of children. Do not swallow. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Clean the skin thoroughly before applying this product.
- Apply a thin layer to affected area once a day before bedtime.
- If bothersome dryness or peeling occurs, reduce application to every other day.
- Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated.

Inactive ingredients

Water, Ethoxydiglycol, Ethylhexyl Palmitate, Cetyl Alcohol, Glycerin, Methyl Methacrylate/Glycol

Dimethacrylate Crosspolymer, PEG-8, Laureth-4, Dimethicone, Aloe Barbadensis Leaf Juice, Polysorbate 80, DEA-Cetyl Phosphate, Polyacrylamide, Propylene Glycol, Sodium Citrate, Bisabolol, C13-14 Isoparaffin, Xanthan Gum, Disodium EDTA, Diazolidinyl Urea, Methylparaben, Propylparaben

Microsponge[®] is a registered trademark of AMCOL International Corp.

Save carton for complete labeling since all warnings are not included on the inner package.

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895

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V-13649

CVS® Quality

Money Back Guarantee

PLEASE RECYCLE

V-31490

#987593

FP409

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AMCOL Health & Beauty Solutions, Inc. DBA AMCOL Household and Personal Care

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lauren.haase@mineralstech.com

Principal Display Panel - 20 g/2 mL Carton Label

SKIN + PHARMACY

ADVANCED

ACNE

THERAPY

OVERNIGHT SALICYLIC ACID LOTION

with Microsponge* Technology

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Overnight Salicylic Acid Lotion Mattifying Lotion

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CVS/pharmacy

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Methacnylater (Glycol Dimethacnylate
Crosspolymer, PEG-8, Laureth-4,
Dimethicone, Aloe Barbadensis Leaf
Juice, Polyscrybate 80, DE-A-Cetyl
Phosphate, Polyacnylamide, Propylene
Glycol, Sodium Citrate, Bisabolol, C13-14
Isoparaffin, Xanthan Gum, Disodium
EDTA, Diazolidinyl Urea, Methylparaben,
Propylparaben

Microsponge® is a registered trademar of AMCOL International Corp. Save carton for complete labeling since all warnings are not included on the inner package.

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CVS Quality

V-31490



Principal Display Panel - 20 g/2 mL Tube Label

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1 FL OZ (30 mL)

Active Ingredient: Salicylic Acid 2% for acne treatment. Warning: For external use only. When using this product Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. only one medication should be used unless directed by a doctor. If product gets into the eyes rinse thoroughly with water In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Directions: Clean skin thoroughly before applying this product. Apply a thin layer to face and neck once a day, before bedtime. **Keep out of reach of children.** Do not swallow. If swallowed, get medical help or contact a Poison Control Center right away

AMCOL International Corp registered trademark of See carton for complete labeling Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 Microsponge® is a Quality and imported components V-31490 1-800-SHOP CVS

SKIN PHARMACY ADVANCED ACNE THERAPY OVERNIGHT SALICYLIC ACID

salicylic acid liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68634-057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
salicylic acid (UNII: O414PZ4LPZ) (salicylic acid - UNII:O414PZ4LPZ)	salicylic acid	20 g in 2 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118 X02B)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
LAURETH-4 (UNII: 6HQ855798J)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIETHANO LAMINE CETYL PHO SPHATE (UNII: 4UG0316V9S)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
1,2-PROPANEDIOL, 1-BENZOATE (UNII: K4K90ZQ89N)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
LEVOMENOL (UNII: 24WE03BX2T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A218 C7H19 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:68634-057-01	1 in 1 CARTON	05/01/2014	
1	30 mL 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	05/01/2014	

Labeler - AMCOL Health & Beauty Solutions, Inc. DBA (872684803)

Establishment			
Name	Address	ID/FEI	Business Operations
AMCOL Health & Beauty Solutions, Inc. DBA		872684803	MANUFACTURE(68634-057), PACK(68634-057), LABEL(68634-057), ANALYSIS(68634-057)

Revised: 6/2016

AMCOL Health & Beauty Solutions, Inc. DBA