

## **ACNE CLEANSER W/ SALICYLIC ACID- salicylic acid cream**

**Allure Labs, 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.*

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### **Drug Facts**

Active Ingredient: Salicylic Acid 2%

Acne Treatment

Uses: Treats acne

dries up acne

help prevent new acne

For external use only.

Do not use :

on the broken skin

if pregnant or lactating

avoid unnecessary sun exposure and use a sunscreen.

do not use in or near the eyes.

not that using other topical acne drugs at the same time or right after use of this product may increase dryness or skin irritation.

Stop use and ask a doctor if too much skin irritation or sensitivity develops or increase.

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

gently massage cleanser onto skin and remove with lukewarm water.

use once daily, alternating use with another, non drug cleanser.

if bothersome dryness or peeling occurs, reduce application to every other day.

store at 19-24 C (66-75 F)

Inactive Ingredients: Water (Aqua), Sorbitol, Ammonium Lauryl Sulfate, Cetyl Alcohol, Stearyl Alcohol, PPG-12/SMDI Copolymer, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Melaleuca Alternifolia (Tea Tree) Leaf Oil.

Physician's Aesthetic Research, Inc Distr.

San Clemente, CA 92672

www.lucrece.com

Made in USA



Innovative Skin Technology

# ACNE CLEANSER W/ SALICYLIC ACID



Net 6 fl. oz. (177 ml)

## Drug Facts

Active Ingredient	Purpose
Salicylic Acid 2%.....	Acne Treatment

**Uses**

- treats acne
- dries up acne
- helps prevent new acne

### Warnings

For external use only

**Do not use**

- on broken skin
- if pregnant or lactating

### When using this product

- avoid unnecessary sun exposure and use a sunscreen
- do not use in or near the eyes
- note that using other topical acne drugs at the same time or right after use of this product may increase dryness or skin irritation.

**Stop use and ask a doctor** if too much skin irritation or sensitivity develops or increases.

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

### Directions

- gently massage cleanser onto skin and remove with lukewarm water.
- use once daily, alternating use with another, non-drug cleanser
- if bothersome dryness or peeling occurs, reduce application to every other day.

**Other information** store at 19-24° C (66-75° F)

**Inactive ingredients:** Water (Aqua), Sorbitol, Ammonium Lauryl Sulfate, Cetyl Alcohol, Stearyl Alcohol, PPG-12/SMDI Copolymer, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Melaleuca Alternifolia (Tea Tree) Leaf Oil

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## ACNE CLEANSER W/ SALICYLIC ACID

salicylic acid cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62742-4107
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4107-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	12/01/2017	

**Labeler** - Allure Labs, Inc (926831603)

**Registrant** - Allure Labs, Inc (926831603)

## Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs, Inc		926831603	manufacture(62742-4107)

Revised: 12/2017

Allure Labs, Inc