

**LEROSETT HIGH-CONTENT ORGANIC ACNE TREATMENT BOTANICALLY BASED-
salicylic acid gel**

Cosmetic Specialty 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.

ACTIVE INGREDIENT

Salicylic Acid 2%

PURPOSE

Acne Treatment

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a poison control center right away.

USES

for treatment of acne

WARNINGS

for external use only

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

Avoid contact with eyes. If contact occurs, flush thoroughly with water.

DIRECTIONS

Use twice a day. Wet face, apply to hands, add water and work: into a lather. Massage into your face, rinse.

INACTIVE INGREDIENTS

Aloe Barbadensis Leaf, Caprylyl Glycol, Cocamidopropyl Betaine, Coco-Glucoside, Fragrance, Glyceryl Oleate, Lauramide DEA, Lauryl Glucoside, Phenoxyethanol, Purified Water, Sodium Citrate, Sodium Lauryl Glucose Carboxylate.

PRINCIPAL DISPLAY PANEL



LEROSETT[®]
High-Content Organic

OTC

Acne Treatment
Face Wash

Botanically Based

6.7 Fl. Oz. (200 mL)

LEROSETT[®] Face Wash is a rare aloe based daily cleanser and acne treatment. Mild, yet highly effective, it thoroughly cleanses and purifies the skin leaving a fresh clean feeling.

Drug Facts

Active Ingredient	Purpose
Salicylic Acid 2%	Acne Treatment

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Directions:

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Inactive ingredients Aloe Barbadensis Leaf, Caprylyl Glycol, Cocamidopropyl Betaine, Coco-Glucoside, Fragrance, Glyceryl Oleate, Lauramide DEA, Lauryl Glucoside, Phenoxyethanol, Purified Water, Sodium Citrate, Sodium Lauryl Glucose Carboxylate.

Manufactured Exclusively for:
Gunilla of Sweden[®]
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5454062

LEROSETT HIGH-CONTENT ORGANIC ACNE TREATMENT BOTANICALLY BASED

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 133-062
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 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL GLYCOL CARBOXYLATE (UNII: 8L0472VMYL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-062-67	200 mL in 1 BOTTLE		
2	NDC:58133-062-13	385 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2013	

Labeler - Cosmetic Specialty labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty labs, Inc.		032973000	manufacture(58133-062)

Revised: 1/2013

Cosmetic Specialty labs, Inc.