

**BLACKHEAD SOLUTIONS SELF-HEATING BLACKHEAD EXTRACTOR ACNE
MEDICATION- salicylic acid cream
CLINIQUE LABORATORIES LLC**

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.

blackhead solutions self-heating blackhead extractor acne medication

Drug Facts

Active ingredient

Salicylic Acid 1.0%

Purpose

Acne Treatment

Uses

- reduces the number of blackheads
- helps keep skin clear of new blackheads
- helps prevent development of new blackheads

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 one topical acne medication should be used unless directed by a doctor.

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

Directions

- Use 3 times a week on clean, dry skin.
- Unscrew top to dispense product.
- Apply thin layer on blackhead-prone areas.
- Reattach top.
- Wet product on skin to activate heat.
- Massage 15-30 seconds with applicator tip, then rinse.

Inactive ingredients

magnesium sulfate • dimethicone • isononyl isononanoate • isododecane • polysilicone-

11 • phenyl trimethicone • hydrogenated lecithin • acetyl glucosamine • polysorbate 20 • polysorbate 80 • polyethylene • diatomaceous earth\solum diatomeae\terre de diatomées • triethylhexanoin • pumice • bambusa arundinacea (bamboo) stem extract • peg-15/lauryl dimethicone crosspolymer • caprylyl glycol • stearyl glycyrrhetinate • water\aquae\eau • silica [iln43644]

PRINCIPAL DISPLAY PANEL - 20 ml Tube Carton

blackheads

CLINIQUE

blackhead

solutions

self-heating

blackhead

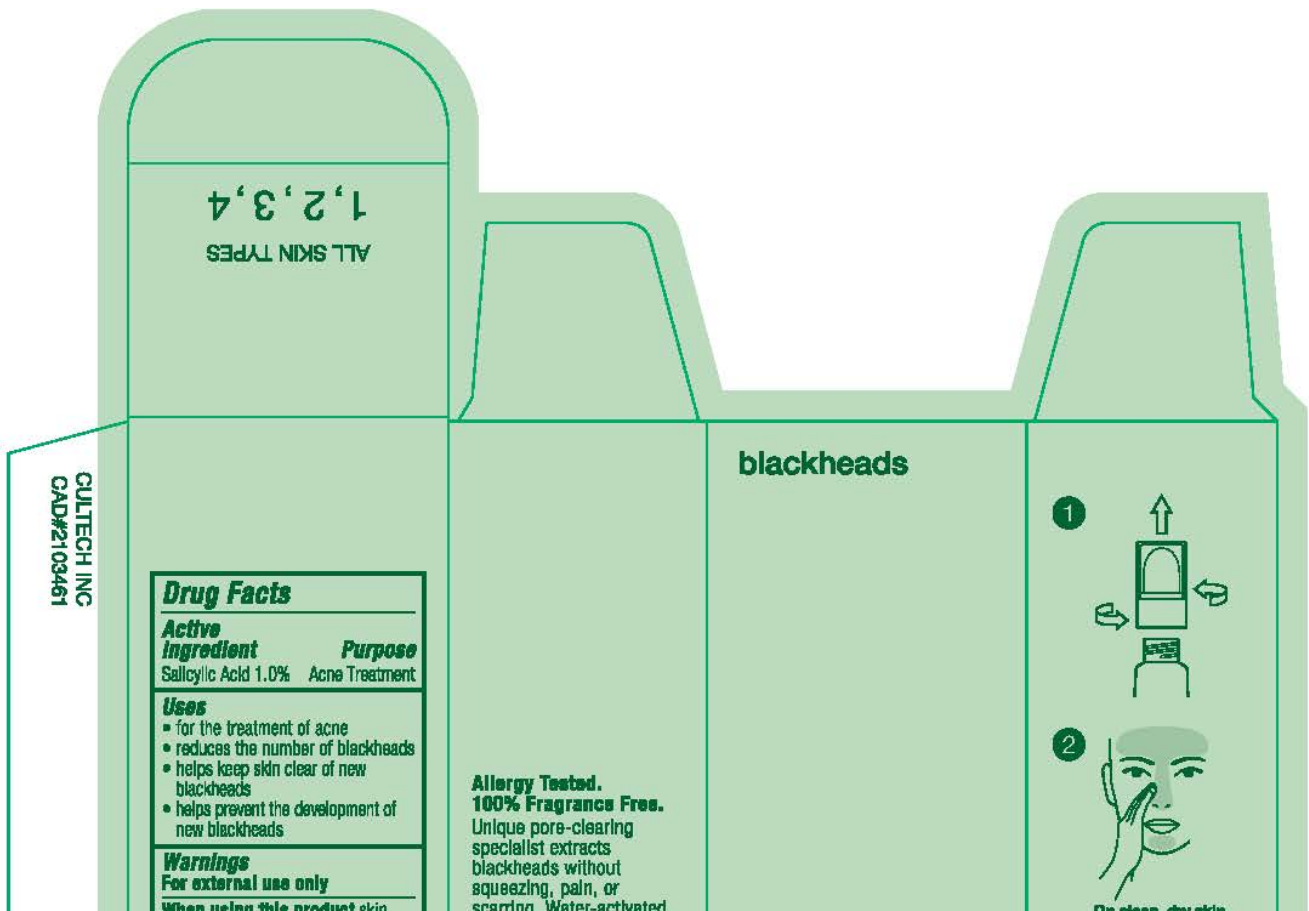
extractor

SALICYLIC ACID

ACNE MEDICATION

ALL SKIN TYPES

.68 FL.OZ.LIQ./20 ml e





BLACKHEAD SOLUTIONS SELF-HEATING BLACKHEAD EXTRACTOR ACNE MEDICATION

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
BAMBUSA BAMBOS STEM (UNII: NRA4497HC5)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
ISODODECANE (UNII: A8289P68Y2)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
PUMICE (UNII: NT5NN5KL16)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-061-01	1 in 1 CARTON	08/30/2018	
1		20 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	08/30/2018	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment

Name	Address	ID/FEI	Business Operations
PALC		078364654	pack(49527-061) , label(49527-061)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Ltd.		204132062	pack(49527-061) , label(49527-061)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder N.V.		370151326	manufacture(49527-061) , pack(49527-061) , label(49527-061)

Establishment

Name	Address	ID/FEI	Business Operations
The Estee Lauder Inc		802599436	pack(49527-061) , label(49527-061) , manufacture(49527-061)

Establishment

Name	Address	ID/FEI	Business Operations
Northtec LLC		943871157	pack(49527-061) , label(49527-061)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	pack(49527-061) , label(49527-061)

Revised: 1/2023

CLINIQUE LABORATORIES LLC