

PROACTIV BLACKHEAD DISSOLVING- salicylic acid gel
Alchemee, LLC

Proactiv ® Blackhead Dissolving Gel

Drug Facts

Active ingredient

Salicylic acid 0.5%

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 eyes. If contact occurs, rinse eyes thoroughly with water.

Keep out of reach of children.

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

Directions

- *Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 uses. If no discomfort occurs, follow the directions stated below.
- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer and rinse thoroughly one to three times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Inactive ingredients

water, dimethicone, cyclopentasiloxane, glycereth-26, glycerin, cyclohexasiloxane, PEG-80 sorbitan laurate, dimethiconol, polyacrylate-13, panthenol, phenoxyethanol, fragrance, polyisobutene, caprylyl glycol, aloe barbadensis leaf juice, butyrospermum parkii (shea) butter, hexylene glycol, ethylhexylglycerin, bisabolol, lactic acid, polysorbate 20, ethylhexyl methoxycinnamate, butyl methoxydibenzoylmethane, PPG-26-buteth-26, PEG-40 hydrogenated castor oil, ethylhexyl salicylate, camellia sinensis leaf extract

Questions or comments?

1-800-950-4695

Distributed by Alchemee LLC

Santa Monica, CA 90401

Made in the USA of Foreign and

Domestic Components

Questions? 1-800-950-4695 • proactiv.com

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Taro Pharmaceuticals U.S.A., Inc.

PRINCIPAL DISPLAY PANEL - 30 mL Tube Box

proactiv®

**BLACKHEAD
DISSOLVING
GEL**

1 FL. OZ. 30 mL

salicylic acid acne medication

<p>Drug Facts</p> <p>Active ingredient Purpose Salicylic acid 0.5%.....Acne treatment</p> <p>Use for the management of acne</p> <p>Warnings For external use only</p> <p>When using this product <ul style="list-style-type: none"> ■ 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 eyes. If contact occurs rinse eyes thoroughly with water </p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions <i>Sensitivity Test for a New User.</i> Apply product sparingly to one or two small affected areas during the first 3 uses. If no discomfort occurs, follow the directions stated below. ■ clean the skin thoroughly before applying this product ■ cover the entire affected area with a thin layer <u>and</u> <u>rinse thoroughly</u> one to three times daily ■ because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor ▶</p>	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ if bothersome dryness or peeling occurs, reduce application to once a day or every other day. <p>Inactive ingredients water, dimethicone, cyclopentasiloxane, glycereth-26, glycerin, cyclohexasiloxane, PEG-80 sorbitan laurate, dimethiconol, polyacrylate-13, panthenol, phenoxyethanol, fragrance, polyisobutene, caprylyl glycol, aloe barbadensis leaf juice, butyrospermum parkii (shea) butter, hexylene glycol, ethylhexylglycerin, bisabolol, lactic acid, polysorbate 20, ethylhexyl methoxycinnamate, butyl methoxydibenzoylmethane, PPG-26-buteth-26, PEG-40 hydrogenated castor oil, ethylhexyl salicylate, camellia sinensis leaf extract</p> <p>Questions or comments? 1-800-950-4695</p> <p>Distributed by Alchemee LLC Santa Monica, CA 90401 Made in the USA of Foreign and Domestic Components Questions? 1-800-950-4695 • proactiv.com</p> <p>Proactiv is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.</p>	<p>proactiv.</p> <p>BLACKHEAD DISSOLVING GEL</p> <p>1 FL. OZ. 30 mL</p> <p>salicylic acid acne medication</p>	<p>Gently formulated to dissolve blackheads, unclog pores, absorb excess oil and deep clean blemish-causing impurities. Designed to soothe irritated skin and shrink the appearance of pores for a more radiant, glowing complexion.</p>
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PROACTIV BLACKHEAD DISSOLVING

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-024
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERETH-26 (UNII: NNE56F2N14)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	

PANTHENOL (UNII: W9CM0067Z)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SHEA BUTTER (UNII: K49155WL9Y)
LEVOMENOL (UNII: 24WE03BX2T)
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)
POLYISOBUTYLENE (1300 MW) (UNII: 241BN7J12Y)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)
AVOBENZONE (UNII: G63QQF2NOX)
OCTINOXATE (UNII: 4Y5P7MUD51)
OCTISALATE (UNII: 4X49Y0596W)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYACRYLAMIDE (1300000 MW) (UNII: SC5Y4X78TG)
PEG-80 SORBITAN LAURATE (UNII: 239B50Y732)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-024-05	1 in 1 BOX	05/01/2013	
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 Drug	M006	05/01/2013	

Labeler - Alchemee, LLC (080216357)

Establishment

Name	Address	ID/FEI	Business Operations
VEE PAK, LLC		874763303	manufacture(11410-024)

Establishment

Name	Address	ID/FEI	Business Operations
Apex International Mfg LLC		079110793	manufacture(11410-024)