

ACNE OIL CONTROL PRIMER- salicylic acid liquid

Allure Labs

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.

Drug Facts

Active Ingredients

Salicylic Acid 2 %

Purpose

Acne Treatment

Uses

For the treatment of acne

Warnings

For external use only

Do not use

If irritation occurs

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.

If bothersome dryness or peeling occurs,

Keep out of reach of children

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

Directions

Clean the skin thoroughly before applying this product

Cover the entire affected area with a thin layer 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

Other Information

Store at 20° - 25°C (68° - 77°F)

Inactive Ingredients

Water (Aqua), Dimethicone, Butylene Glycol, Dimethicone Crosspolymer, Ammonium Polyacryloyldimethyl Taurate, Hydroxyethylcellulose, Serenoa Serrulata (Saw Palmetto) Fruit Extract, Sodium Ascorbyl Phosphate, Niacinamide, Linoleic Acid, Linolenic Acid, Docosahexaenoic Acid, Eicosapentaenoic Acid, Nigella Sativa (Black Cumin) Seed Oil, Scutellaria Baicalensis Root Extract, Zinc Gluconate, Glycerin, Tocopherol, Oleanolic Acid, Enantia Chlorantha Bark Extract, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Disodium Phosphate, Phenoxyethanol, Polysorbate 60, Sodium Hydroxide, Sodium Phosphate.

<p>Drug Facts</p>	<p>Drug Facts <i>(continued)</i></p>	<div style="text-align: center;">  <p>ACNE & OIL CONTROL PRIMER</p> <p>2% SALICYLIC ACID</p> <p>DERMATOLOGIST FORMULATED</p> <p>1.5 OZ (45g)</p> </div>	<p>Hormones, diet, and stress all contribute to acne breakouts. With this in mind, JORXI was formulated with Dermatologist approved, scientifically selected ingredients to address your skin's unique needs.</p> <p>This medicated primer treats acne with salicylic acid, controls shine, and helps reduce the appearance of pores.</p> <p>Free of fragrances, dyes, parabens, phthalates, and sulfates.</p> <p>@joriskincare</p>
<p>Active Ingredients Salicylic Acid (2%)</p> <p>Purpose Acne Treatment</p> <p>Uses For the treatment of acne</p> <p>Warnings</p> <ul style="list-style-type: none"> • 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. • Keep out of reach of children If product is swallowed, get medical help or contact a Poison Control Center right away. <p>Directions</p> <ul style="list-style-type: none"> • Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer 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 <p>Other Information ▶ Store at 20°-25°C (68°-77°F)</p>	<p>Inactive Ingredients Water (Aqua), Dimethicone, Butylene Glycol, Dimethicone Crosspolymer, Ammonium Polyacryloyldimethyl Taurate, Hydroxyethylcellulose, Serenoa Serrulata (Saw Palmetto) Fruit Extract, Sodium Ascorbyl Phosphate, Niacinamide, Linoleic Acid, Linolenic Acid, Docosahexaenoic Acid, Eicosapentaenoic Acid, Nigella Sativa (Black Cummin) Seed Oil, Scutellaria Baicalensis Root Extract, Zinc Gluconate, Glycerin, Tocopherol, Oleic Acid, Enantia Chlorantha Bark Extract, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Disodium Phosphate, Phenoxyethanol, Polysorbate 60, Sodium Hydroxide, Sodium Phosphate.</p> <p>Questions or Comments? Visit www.joriskincare.com or email hello@joriskincare.com</p>		

ACNE OIL CONTROL PRIMER			
salicylic acid liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4211
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 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ANNICKIA CHLORANTHA BARK (UNII: H70115MP4A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
SAW PALMETTO (UNII: J7WWH9M8QS)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DOCONEXENT (UNII: ZAD9OKH9JC)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
LINOLENIC ACID (UNII: 0RBV727H71)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ICOSAPENT (UNII: AAN7QOV9EA)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4211-2	1 in 1 CARTON	04/01/2022	
1	NDC:62742-4211-1	45 g 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	04/01/2022	

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4211)

Revised: 4/2022

Allure Labs