

SALICYLACNE-1% CLEARING GEL- salicylic acid gel
Valley of the Sun Cosmetics

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.

Salicylacne-1% Clearing Gel

Active Ingredients

Salicylic Acid 1%

Purpose

Acne Treatment

Uses

Use for treatment of acne

Warning

For external use only

Do not use

Allergy alert: Do not use this product if you have a known allergy to salicylic acid

When using this product

Skin irritation and dryness is more likely 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, flush thoroughly with water.

Keep out of reach of children

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

Directions

Apply with a cotton ball, sweeping gently over face and neck (Cover the entire affected area with a thin layer) one to two times daily. If dryness or peeling occurs, reduce usage to every other day. It is best for normal, dry, combination and oily skin.

Inactive ingredients

Water(aqua), Propylene glycol, Glycerin, Acetyl glutathione (glutamine), Acrylates/C10-30 alkyl acrylates crosspolymer, Denatured alcohol (40-B), Benzoyl peroxide, Lactic acid, Polysorbate 20, Melaleuca alternifolia (*organic tea tree) leaf oil, Camelia sinesis (*organic green tea)leaf extract, Retinyl Palmitate (vitamin A), Carica (*organic papaya) fruit extract, Sodium ascorbyl phosphate (vitamin C), Bromelain (*organic pineapple steam leaf), Sodium PCA, Allium sativum (*organic garlic) oil, Citrus medica limonium (*organic lemon) fruit extract), Sodium hydroxide, Phenoxyethanol, Glycolic acid, Fragrance parfum

Package Label



SALICYLACNE-1% CLEARING GEL

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76523-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

(2S)-3-PHENYLPROPANE-1,2-DIOL (UNII: 6PQ7U3G5W6)
ALLIUM SATIVUM WHOLE (UNII: IIF21WT8O3)
GLYCERIN (UNII: PDC6A3C0OX)
BENZOYL PEROXIDE (UNII: W9WZN9A0GM)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
GLYCOLIC ACID (UNII: 0WT12SX38S)
SODIUM PIDOLATE (UNII: 1V74VH163T)
LACTIC ACID (UNII: 33X04XA5AT)
GLUTAMINE (UNII: 0RH81L854J)
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)
ALCOHOL (UNII: 3K9958V90M)
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
VITAMIN A (UNII: 81G40H8B0T)
CARICA PAPAYA WHOLE (UNII: S0U63B0Q51)
STEM BROMELAIN (UNII: ZLM4P8929R)
CITRUS MEDICA FRUIT (UNII: ZE5Q6PN9ON)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)

Product Characteristics

Color		Score	
Shape	ROUND	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76523-107-02	59.15 mL in 1 JAR; Type 0: Not a Combination Product	06/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/17/2021	

Labeler - Valley of the Sun Cosmetics (176470664)

Registrant - Valley of the Sun Cosmetics (176470664)

Establishment

Name	Address	ID/FEI	Business Operations
Valley of the Sun Cosmetics LLC		176470664	manufacture(76523-107)

Revised: 6/2021

Valley of the Sun Cosmetics