

## **DERMACLEAR SERUM- salicylic acid cream**

**Allure 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.*

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### **Drug Facts**

Active Ingredients: Salicylic Acid 2%

Purpose: Acne Treatment

Uses:

For the treatment 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.

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 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 doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- Sensitivity Test for a new users. Apply product sparingly to one or two small affected areas during first 3 days. If no discomfort occurs, follow the directions stated above.

Other Information:

Protect the product in this container from the excessive heat and direct sun.

Water (Aqua), Alcohol Denat., Glycolic Acid, Caprylic / Capric Triglyceride, Azelaic Acid, Glycerin, Hexyl Laurate, Cetearyl Alcohol, Cetearyl Oliviate, Butylene Glycol, Sorbitol, Lactic Acid, Sorbitan Oliviate, PPG-12 /SMDI Copolymer, Niacinamide, Cetyl Alcohol, Sodium Hyaluronate, Dicetyl Phosphate, Ceteth-10 Phosphate, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Tocopheryl Acetate, Butyrospermum Parkii (Shea) Butter, Mangifera Indica (Mango) Seed Butter, Dimethicone, Ethyl Linoleate, Hexylsorbic Acid, Yeast Polysaccharides, Propylene Glycol, Symphytum Officinale Rhizome/Root Extract, Plantago Ovata Seed Extract, Glutamine, Proline, Leucine, Serine, Hedera, Helix (Ivy) Leaf/Stem Extract, Cucumis Sativus Fruit Extract, Sambucus Nigra Flower Extract, Arnica Montana Flower Extract, Parietaria Officinalis Extract, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerine, Hexylene Glycol, Lavandula Angustifolia (Lavender) Oil, Imperata Cylindrica (Root) Extract, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Malva Sylvestris (Mallow) Extract, Mentha Piperita (Peppermint) Leaf Extract, Primula Veris Extract, Alchemilla Vulgaris Extract, Veronica Officinalis Extract, Melissa Officinalis Leaf Extract, Achillea Millefolium Extract, Hydrolyzed Vegetable Protein, Glycosaminoglycans, Salix Alba (Willow) Bark Extract, Arcapostaphylos, Uva Ursi Leaf Extract, Mitracarpus Scaber Extract, PEG-60 Almond Glycerides, Nordihydroguaiaretic Acid, Oleanolic Acid, Glycerin, Hydrolyzed wheat Protein, Hydrolyzed Wheat Starch, Maltodextrin, Syringa Vulgaris (Lilac) Leaf Cell Culture Extract, Xanthan Gum, Magnesium Aluminum Silicate, Ammonium Hydroxide,

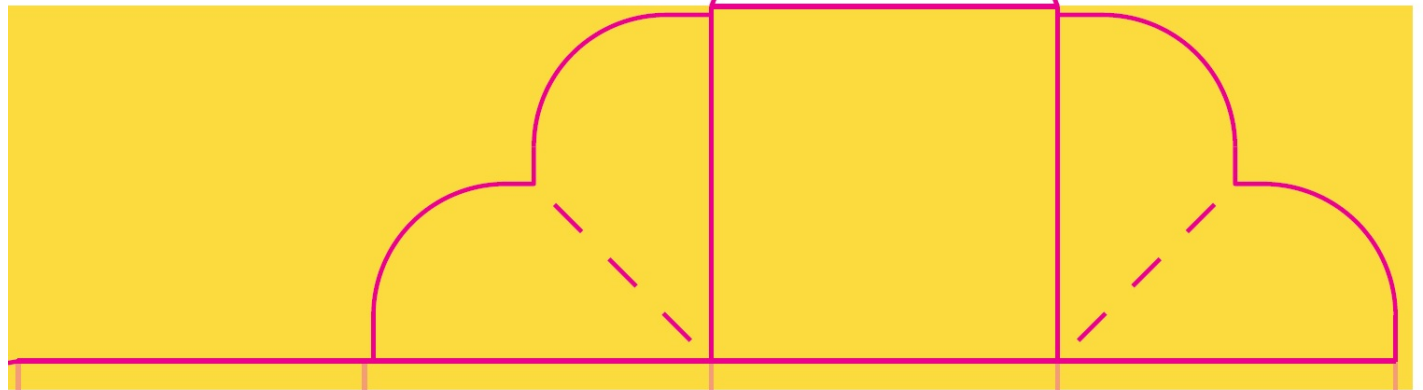
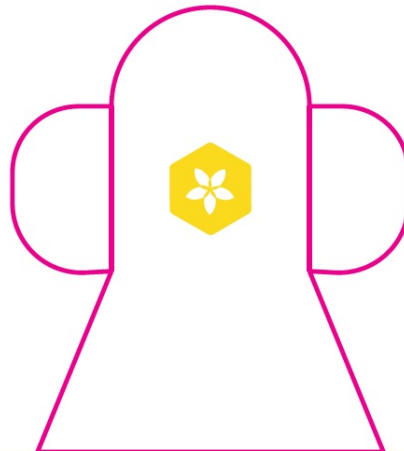
Disodium EDTA, Linalool

Manufactured for Dermaquest Inc

Hayward, CA 94544

1272 GK, NL Made in USA

dermaquestinc.com



Salicylic Acid acne medication

**DRUG FACTS**

Active Ingredients Salicylic Acid 2 %  
Purpose Acne Treatment

**Uses**

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Manufactured for DermaQuest®, Inc.  
Hayward, CA 94544  
1272 GK,NL Made in USA  
dermaquestinc.com

**DIRECTIONS:**  
Apply using fingertips and gently massage into skin, avoiding the eye area. Must be supported with a committed use of daily SPF. Not recommended for those with aspirin/NSAID allergies.

Can be used AM/PM. AM use must be used under SPF 30 or higher.



DermaClear  
Serum  
DermaClear

Clear and control breakouts with our signature anti-acne serum without over drying. A combination of Alpha and Beta Hydroxy Acids purify and exfoliate, while reducing the pore-clogging oils that cause future blemishes. The hydrating MDI Complex® keeps skin supple, dewy and smooth.



1 FL OZ / 29.6 mL



**DERMACLEAR SERUM**

salicylic acid cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62742-4069
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL
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## Inactive Ingredients

Ingredient Name	Strength
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
YEAST (UNII: 3NY3SM6B8U)	
PROLINE (UNII: 9DLQ4CIU6V)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBITOL (UNII: 506T60A25R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLUTAMINE (UNII: 0RH81L854J)	
LEUCINE (UNII: GMW67QNF9C)	
SERINE (UNII: 452VLY9402)	
HEDERA HELIX LEAF (UNII: ZP9XFG71A7)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
MALVA SYLVESTRIS FLOWERING TOP (UNII: X1U1U0N90J)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ALCHEMILLA XANTHOCHLORA FLOWERING TOP (UNII: 9M289NKI69)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
PARIETARIA OFFICINALIS LEAF (UNII: W2I83529KR)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
PRIMULA VERIS (UNII: W6LFQ57E4M)	
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
HEXYLRESORCINOL (UNII: R9QTB5E82N)	
COMFREY ROOT (UNII: M9VVZ08EKQ)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
VERONICA OFFICINALIS FLOWERING TOP (UNII: 9IH82J936J)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
GAG (UNII: U5T7CTT5KM)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	

DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)
STEARIC ACID (UNII: 4ELV7Z65AP)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
ARCTOSTAPHYLOS UVA-URSILEAF (UNII: 3M5V3D1X36)
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)
NORDIHYDRO GUAIARETIC ACID, (+/-)- (UNII: 7PZ73W4ZNR)
PEG-100 STEARATE (UNII: YD01N1999R)
MITRACARPUS HIRTUS WHOLE (UNII: 57P5O8083D)
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
SYRINGA VULGARIS WHOLE (UNII: U49SHU1VCI)
XANTHAN GUM (UNII: TTV12P4NEE)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
AMMONIA (UNII: 5138Q19F1X)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCOLIC ACID (UNII: 0WT12SX38S)
AZELAIC ACID (UNII: F2VW3D43YT)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
SHEA BUTTER (UNII: K49155WL9Y)
ETHYL LINOLEATE (UNII: MJ2YTT4J8M)
PLANTAGO OVATA SEED (UNII: UD50RBY30F)
CUCUMBER (UNII: YY7C30VXJT)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
LINALOOL, (+/-)- (UNII: D81QY6I88E)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4069-2	1 in 1 CARTON	05/30/2014	
1	NDC:62742-4069-1	29.6 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 final	part333D	05/30/2014	

**Labeler** - Allure Labs Inc (926831603)

**Registrant** - Allure Labs Inc (926831603)

### Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs Inc		926831603	manufacture(62742-4069)