

TIEGE HANLEY DAILY MOISTURIZING ACNE- salicylic acid cream
TIEGE HANLEY,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.

Tiège Hanley Daily Moisturizing Acne Cream

Drug Facts

Active Ingredients

Salicylic Acid 1.6%

Purpose

Acne Treatment

Uses

- For the management of acne

Warnings

- For External Use Only

When using this product

- do not use this product more than twice per day
- discontinue use if skin irritation occurs
- avoid contact with eyes
- if going outside, apply sunscreen after using this product
- skin irritation and dryness are more likely to occur if you use more than one acne medication at the same time
- if irritations occur only use one topical acne medication at a time
- avoid aggressive soaps if irritations are experienced

Do not use if you

- have very sensitive skin
- are sensitive to salicylic acid

Stop use and ask a doctor if irritation becomes severe

Keep out of reach of children

- if swallowed, get medical help or contact a Poison Control Center right away

Directions

- Clean face thoroughly with Tiege Hanley WASH before applying this product
- Dispense approximately 3 pumps—enough to cover the entire affected area with a thin layer, including the face and neck
- For best results, use before bedtime
- For severe acne, add morning application after WASH, only if followed by AM moisturizer with SPF 20
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two times daily if needed or as directed by a doctor
- If bothersome dryness or peeling occurs, reduce application to once per day or every other day

Inactive Ingredients

Aqua, Glycerin, Cyclopentasiloxane, Cocamidopropyl Dimethylamine, Ethyl Palmate, Behenyl Alcohol, Zea Mays (Corn) Starch, Beheneth-5, Polyglyceryl-3 Stearate, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, Caprylyl Glycol, Cetareth-25, Medicago Sativa (Alfalfa) Extract, Plantago Major Leaf Extract, Calendula Officinalis Flower Extract, Aleurites Moluccanus Seed Oil, Xanthan Gum, Sodium Hyaluronate

Other Information

- When not using, keep at room temperature with the cap closed
- Distributed by Tiege Hanley, Inc.
Chicago, IL 60612

PRINCIPAL DISPLAY PANEL - 24 g Bottle Label

TIÉGE
HANLEY

Uncomplicated
Skin Care for Men®

ACNE

Daily Moisturizing
Acne Cream

Net Wt 0.85 oz (24 g)



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Drug Facts (continued)

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Defend YOUR LARGEST ORGAN™

Made in the USA ■ Distributed by Tiegé Hanley, Inc.
Chicago, IL 60612 ■ Tiegé.com

210137

TIEGE HANLEY DAILY MOISTURIZING ACNE

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71714-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	16 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STARCH, CORN (UNII: 08232NY3SJ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	

POLYGLYCERYL-3 STEARATE (UNII: 8FDA8C98S3)
BEHENETH-5 (UNII: L4A971L76E)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
CETEARETH-25 (UNII: 8FA93U5T67)
ETHYL PALMATE (UNII: PY7890FR5M)
DOCOSANOL (UNII: 9G1OE216XY)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
ALFALFA TOP (UNII: SQI2NBY9KR)
PLANTAGO MAJOR LEAF (UNII: 7DC28K241X)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
KUKUI NUT OIL (UNII: TP11QR7B8R)
COCAMIDOPROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)

Product Characteristics

Color	WHITE (off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71714-002-24	24 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/01/2018	

Labeler - TIEGE HANLEY,Inc. (080305325)

Establishment

Name	Address	ID/FEI	Business Operations
BMC 1092, Inc. dba Solo Laboratories, Inc		078831987	MANUFACTURE(71714-002) , PACK(71714-002)