

GOODBYE ACNE COMPLETE TREATMENT GEL- salicylic acid gel

Peter Thomas Roth, LLC

GOODBYE ACNE Complete treatment gel

Active Ingredient

Salicylic Acid 2%

Active Ingredient Purpose

Salicylic Acid 2%.....Acne treatment

Uses

- For the treatment and management of acne.
- Clears up acne blemishes and blackheads.
- Helps prevent new acne blemishes and blackheads.

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, flush thoroughly with water.

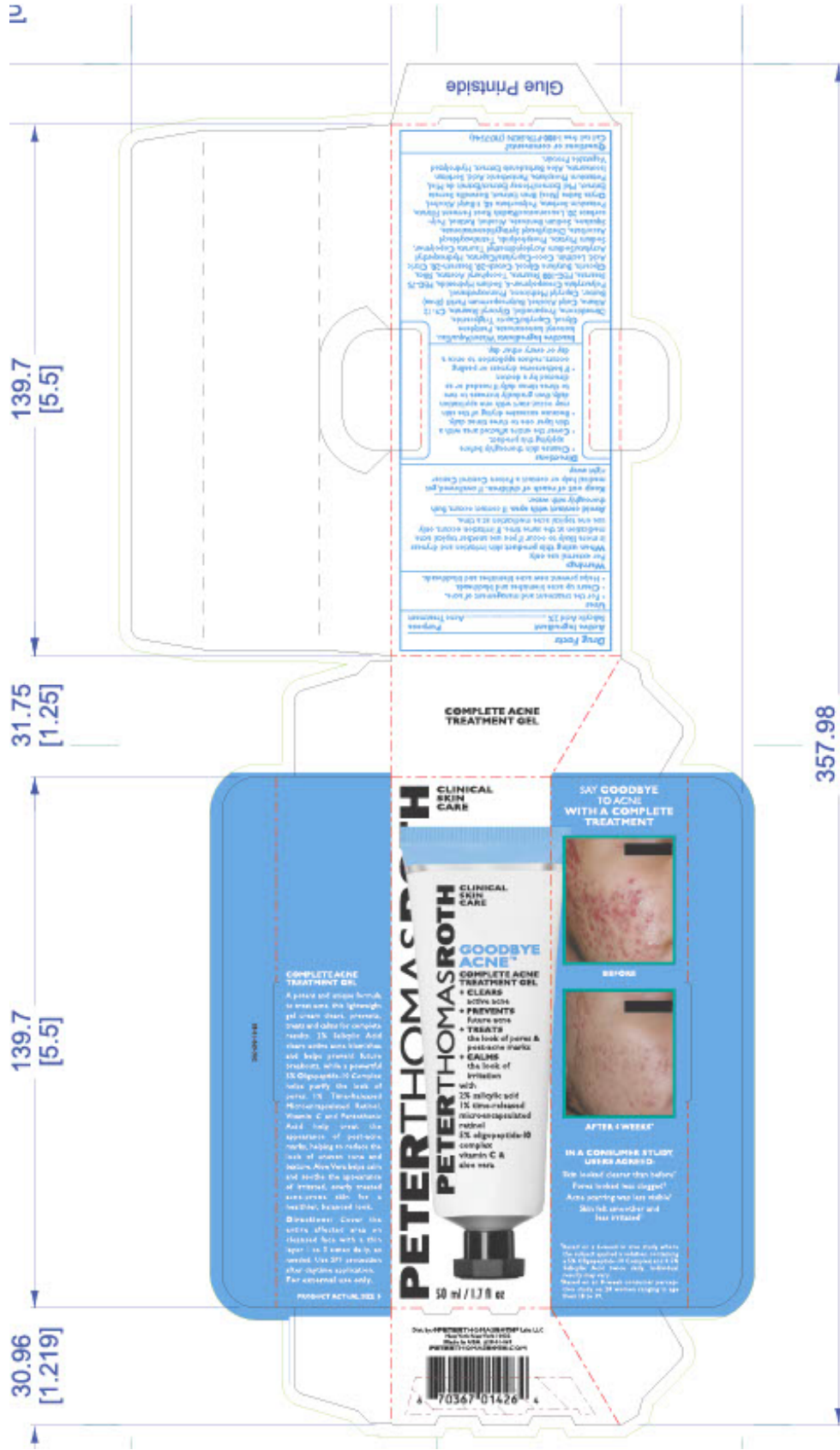
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control center right away.

Directions

- Cleanse 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, the gradually increase to two to three times daily if needed or as direrected by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Inactive Ingredients

Water/Aqua/Eau, Isononyl Isononanoate, Pentylene Glycol, Caprylic/Capric Triglyceride, Dimethicone, Propanediol, Glyceryl Stearate, C9-12 Alkane, Cetyl Alcohol, Butyrospermum Parkii (Shea) Butter, Caprylyl Methicone, Phenoxyethanol, Polyacrylate Crosspolymer-6, Sodium Hydroxide, PEG-75 Stearate, PEG-100 Stearate, Tocopheryl Acetate, Silica, Glycerin, Butylene Glycol, Ceteth-20, Steareth-20, Citric Acid, Lecithin, Coco-Caprylate/Caprates, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Sodium Phytate, Phospholipids, Tetrahexyldecyl Ascorbate, Diethylhexyl Syringylidenemalonate, Squalane, Sodium Benzoate, Alcohol, Retinol, Polysorbate 20, Leuconostoc/Radish Root Ferment Filtrate, Potassium Sorbate, Polysorbate 60, t-Butyl Alcohol, Oryza Sativa (Rice) Bran Extract, Boswellia Serrata Extract, Honey Extract, Potassium Phosphate, Pantothenic Acid, Sorbitan Isostearate, Aloe Barbadensis Extract, Hydrolyzed Vegetable Protein



in

139.7 [5.5]

31.75 [1.25]

139.7 [5.5]

30.96 [1.219]

Glue Printside

Drug Facts
 Important information about this medicine and what to do to keep you safe.
 Read the entire label, including the information about ingredients, warnings, and directions. Do not use this medicine if you are allergic to any of the ingredients listed here, or if you have ever had an allergic reaction to any of the ingredients listed here. Do not use this medicine if you are pregnant, planning to get pregnant, or are breastfeeding. Tell your doctor about all the medicines you are taking, including over-the-counter medicines, vitamins, and herbal products. Tell your doctor if you are taking or plan to take any medicine that may affect the heart, such as digoxin (Lanoxin), amiodarone (Cordarone), or sotalol (Betapac). Tell your doctor if you are taking or plan to take any medicine that may affect the liver, such as acetaminophen (Tylenol), alcohol, or certain antibiotics. Tell your doctor if you are taking or plan to take any medicine that may affect the kidneys, such as NSAIDs, certain antibiotics, or certain diuretics. Tell your doctor if you are taking or plan to take any medicine that may affect the blood, such as aspirin, ibuprofen (Advil), or certain anticoagulants. Tell your doctor if you are taking or plan to take any medicine that may affect the eyes, such as contact lenses or eye drops. Tell your doctor if you are taking or plan to take any medicine that may affect the skin, such as retinoids or tetracyclines. Tell your doctor if you are taking or plan to take any medicine that may affect the stomach, such as acid reducers or laxatives. Tell your doctor if you are taking or plan to take any medicine that may affect the immune system, such as corticosteroids. Tell your doctor if you are taking or plan to take any medicine that may affect the blood sugar, such as insulin or oral diabetes pills. Tell your doctor if you are taking or plan to take any medicine that may affect the thyroid, such as levothyroxine (Synthroid). Tell your doctor if you are taking or plan to take any medicine that may affect the heart rate, such as beta-blockers or calcium channel blockers. Tell your doctor if you are taking or plan to take any medicine that may affect the lungs, such as bronchodilators or steroids. Tell your doctor if you are taking or plan to take any medicine that may affect the bones, such as bisphosphonates. Tell your doctor if you are taking or plan to take any medicine that may affect the liver enzymes, such as grapefruit juice. Tell your doctor if you are taking or plan to take any medicine that may affect the stomach acid, such as proton pump inhibitors. Tell your doctor if you are taking or plan to take any medicine that may affect the kidneys, such as NSAIDs or certain antibiotics. Tell your doctor if you are taking or plan to take any medicine that may affect the blood, such as aspirin or NSAIDs. Tell your doctor if you are taking or plan to take any medicine that may affect the heart, such as beta-blockers or calcium channel blockers. Tell your doctor if you are taking or plan to take any medicine that may affect the lungs, such as bronchodilators or steroids. Tell your doctor if you are taking or plan to take any medicine that may affect the bones, such as bisphosphonates. Tell your doctor if you are taking or plan to take any medicine that may affect the liver enzymes, such as grapefruit juice. Tell your doctor if you are taking or plan to take any medicine that may affect the stomach acid, such as proton pump inhibitors.

COMPLETE ACNE TREATMENT GEL

CLINICAL SKIN CARE

GOODBYE ACNE™

PETER THOMAS ROTH COMPLETE ACNE TREATMENT GEL

CLINICAL SKIN CARE

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357.98 [14.094]

SAY GOODBYE TO ACNE WITH A COMPLETE TREATMENT



BEFORE



AFTER 4 WEEKS

IN A CONSUMER STUDY, USERS AGREED: 'I've looked clearer than before!' 'Pores looked less clogged!' 'Acne severity had less impact!' 'Skin felt smoother and less irritated.'

Based on a 4-week in-use study which included pre-treatment and follow-up. *See clinical data for details. ©2011 Peter Thomas Roth, Inc. All rights reserved.

See back of tube for directions. Use only after cleansing and drying skin.

10 ml / 0.33 fl. oz.

7036701426

Mechanical File	PETER THOMAS ROTH CLINICAL SKIN CARE	460 Park Ave. 16 th fl., New York, NY 10022
FILE SPECS	ARTWORK SPECS	APPROVALS
FILE NAME: PTR USA 18-01-089-902_Crtn_210330A PATH: Art Dept/PTRV Packaging/PTR USA 18-01-089 Acne-Clear 390/ CARTON/1st Submission/1st Revision	COLORS BREAKDOWN: BLACK TEXT 100% K PMS 284C IMAGES CMYK Process Die (do not print) SPOT GLOSS 100% Magenta SILVER FOIL STAMP	STOCK: 018 SBS Soft Touch COMPONENT: NOTES TO PRINTER: Pre-Press Proof required for APPROVAL
DELINE: 2 1/4" W x 5 1/2" H x 1 1/4" D DECO AREA: UPC #: 6-70367-01425-4 DATE: 01/21/21 ART RELEASE DATE: 03/00/21 DESIGNER: PRE-PRODUCTION DESIGNER: Susan Cheng		OFFR MKTG PROD DEV PKG DEV REG/ R&D CREATIVE PTR JVC/MGH SL ME/BJ BG DH
CONTACT: David Held	EMAIL: dheid@peterthomasroth.com	PHONE: 212.581.5800 ext. 5808

GOODBYE ACNE COMPLETE TREATMENT GEL

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54031-069
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.9638 g in 48.19 g

Inactive Ingredients

Ingredient Name	Strength
PEG-75 STEARATE (UNII: OT38R0N74H)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALCOHOL (UNII: 3K9958V90M)	
HONEY (UNII: Y9H1V576FH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)	
WATER (UNII: 059QF0KO0R)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
C9-12 ALKANE (UNII: 7J5R5W72QM)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

SHEA BUTTER (UNII: K49155WL9Y)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PROPANEDIOL (UNII: 5965N8W85T)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
PHYTATE SODIUM (UNII: 88496G1ERL)
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)
RICE BRAN (UNII: R60QEP13IC)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
GLYCERIN (UNII: PDC6A3C0OX)
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)
RETINOL (UNII: G2SH0XKK91)
POLYSORBATE 60 (UNII: CAL22UVI4M)
CETETH-20 (UNII: I835H2IHHX)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)
STEARETH-20 (UNII: L0Q8IK9E08)
SQUALANE (UNII: GW89575KF9)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ALOE (UNII: V5VD430YW9)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PANTOTHENIC ACID (UNII: 19F5HK2737)
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54031-069-01	48.19 g in 1 TUBE; Type 0: Not a Combination Product	06/15/2021	
2	NDC:54031-069-02	48.19 g in 1 CARTON; Type 0: Not a Combination Product	06/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	06/15/2021	

Labeler - Peter Thomas Roth, LLC (780458944)

Registrant - June Jacobs Labs, LLC (122610681)

Establishment

Name	Address	ID/FEI	Business Operations
June Jacobs Labs, LLC		122610681	manufacture(54031-069)

Revised: 11/2023

Peter Thomas Roth, LLC