

PREP EVERYDAY CLEAR ACNE- salicylic acid acne treatment solution
PREP Cosmetics LLC

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.

PREP Acne Treatment

Active Ingredient

Salicylic acid 1%

Purpose

Acne medication

Use

For the treatment of acne

Warnings

- **For external use only.**
- **When using this product:** Skin irritation or 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.
- Rinse right away with water if it gets in the eyes.

Keep out of reach of children

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

Directions

- Clean the skin thoroughly before applying the 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.

Sensitivity Test for a New User

Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the directions stated elsewhere on this label.

Azelaic Acid, Butylene Glycol, Chamaemelum Nobile Flower Oil, Ethylhexylglycerin, Geranium Maculatum Root Oil, Hydroxyethyl Cellulose, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Hydroxypropyl Distarch Phosphate, High Amylose Corn, Lavender Oil, Mandelic Acid, PEG-12 Glyceryl Dimyristate, PEG-23 Glyceryl Distearate, Phytate Sodium, Polysorbate 60, Potassium Sorbate, Propanediol, Rosa Canina Fruit, Salix Nigra Bark, Sorbitol, Squalane, Water

Other Information

- Store at room temperature

Questions?

Call toll free 1-800-401-6031

www.prepyourskin.com



Product Information Item: PREP ACNE Eval: X2032827 Cust: PREP COSMETICS LLC Size: 1.2500x1.2500x4.5000 Sample #: 031077 Braille: NA	Specified Colors 	Approved By Name _____ Date _____ <input type="checkbox"/> OK to Print <input type="checkbox"/> New Proof Required We must have signed proof before we can begin production. <small>This proof is to show size, copy placement and color break. Spot/PMS colors will be matched on press to: PMS Book, 4 Color Process Digital Color Guide, Extended Gamut Digital Color Guide and/or approved color standards. 4 Color Process proofs are verified to G7 standards and approved for color match.</small>
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PREP EVERYDAY CLEAR ACNE

salicylic acid acne treatment solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70231-0017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
GERANIUM MACULATUM ROOT OIL (UNII: H2E371EDYX)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
PEG-12 GLYCERYL DIMYRISTATE (UNII: VS4W16AQ3X)	
SALIX NIGRA BARK (UNII: QU52J3A5B3)	
HYDROXYPROPYL DISTARCH PHOSPHATE, HIGH AMYLOSE CORN (UNII: 9F8ET54T05)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
PEG-23 GLYCERYL DISTEARATE (UNII: 527412VE0U)	
SORBITOL (UNII: 506T60A25R)	
HYDROXYETHYL CELLULOSE (4000 CPS AT 1%) (UNII: ZYD53NBL45)	
MANDelic ACID (UNII: NH496X0UJX)	
AZELAIC ACID (UNII: F2VW3D43YT)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70231-0017-1	1 in 1 CARTON	11/06/2015	
1		30 mL in 1 BOTTLE; 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	11/06/2015	

Labeler - PREP Cosmetics LLC (053793815)

Registrant - Richard Hamer Associates LLC (067731889)

Establishment

Name	Address	ID/FEI	Business Operations
Taka USA, Inc dba Cosmetic Innovations		802860515	manufacture(70231-0017) , pack(70231-0017)

Revised: 10/2018

PREP Cosmetics LLC