DUAL EFFECTS MOISTURIZER- salicylic acid lotion Fruit of the Earth, 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.

SPACOLOGY DUAL EFFECTS MOISTURIZER

Active Ingredient

Salicylic Acid 0.25%

Purpose

Acne Medication

Uses

• For the management 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 medicaton at the same time. If irritation occurs, only use one topical acne medicaton at a time.
- avoid contact with eves. If contact occurs, flush thoroughly with water

Keep out of reach of children

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

Directions

- Cleanse skin throughly before applying this product
- Cover the entire affected area with a think layer one to three times daily
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two to three times daily a needed or as directed by doctor.
- If bothersome dryness or peelin ocur, reduce application to once a day or every other day.

Other information

• may stain some fabrics

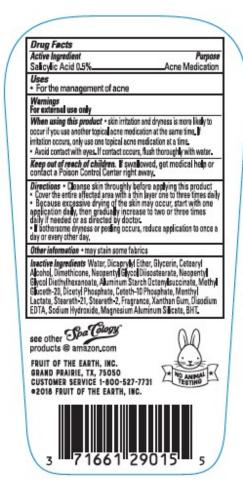
Inactive ingredients

Water, Dicaprylyl Ether, Glycerin, Cetearyl Alcohol, Dimethicone, Neopentyl Glycol Diisostearate, Neopentyl Glycol Diethylhexanoate, Aluminum Starch Octenylsuccinate, Methyl Gluceth-20, Dicetyl Phosphate, Ceteth-10 Phosphate, Mentyl Lacatate, Steareth-21, Steareth-2, Fragrance, Xanthan Gum, Disodium EDTA, Sodium Hydroxide, Magnesium Aluminum Silicate, BHT.

Label

Spacology Dual Effects Moisturizer 4 fl oz (118 mL) NDC 62217-158-04





DUAL EFFECTS MOISTURIZER

salicylic acid lotion

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:62217-158

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthSALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII: O414PZ4LPZ)SALICYLIC ACID5 mg in 1 mL

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19PJ0 O 6 2 9 4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6 M3P6 4V0 NC)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIHEXADECYL PHO SPHATE (UNII: 2V6E5WN99N)	
CETETH-10 PHO SPHATE (UNII: 4E05O5N49G)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
NEOPENTYL GLYCOL DIISOSTEARATE (UNII: 4M6 O Q 34 J W W)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:62217-158- 04	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/15/20 17		

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part333D	11/15/2017					

Labeler - Fruit of the Earth, Inc. (079559467)

Revised: 2/2021 Fruit of the Earth, Inc.