

## **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.*

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## **SPACOLGY 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 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, then gradually increase to two to three times daily as needed or as directed by doctor.
- If bothersome dryness or peeling occurs, 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, Dicaprylyl Phosphate, Ceteth-10 Phosphate, Mentyl Lactate, 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

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-158
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

EDETATE DISODIUM (UNII: 7FLD91C86K)
METHYL GLUCETH-20 (UNII: J3QD0LD11P)
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)
XANTHAN GUM (UNII: TTV12P4NEE)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
GLYCERIN (UNII: PDC6A3C0OX)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)
DIMETHICONE (UNII: 92RU3N3Y1O)
NEOPENTYL GLYCOL DIISOSTEARATE (UNII: 4M6OQ34JWW)
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)
STEARETH-2 (UNII: V56DFE46J5)
STEARETH-21 (UNII: 53J3F32P58)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
DICAPRYLYL ETHER (UNII: 77JZM5516Z)
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62217-158-04	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/15/2017	

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)