SOLIMO REPAIRING TREATMENT FOR ACNE PRONE SKIN- benzoyl peroxide liquid Amazon.com Services 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.

Solimo Repairing Treatment For Acne Prone Skin

Drug Facts

Active Ingredient

Benzoyl Peroxide 2.5%

Purpose

Acne treatment gel

Uses

for the management of acne

Warnings

For external use only.

When using this product:

- do not use this product more than three times per day.
- skin irritation and dryness are 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 unnecessary sun exposure and use a sunscreen.
- avoid contact with the eyes, lips, and mouth.
- avoid contact with hair and dyed fabrics, which may be bleached by this product.
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Do not use

if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

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

- *Sensitivity Test for a New User:* Apply product sparinglyto one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- cleanse the 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 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.
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Inactive Ingredients

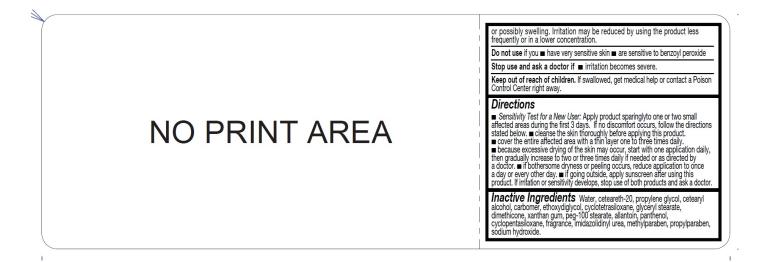
Water, ceteareth-20, propylene glycol, cetearyl alcohol, carbomer, ethoxydiglycol, cyclotetrasiloxane, glyceryl stearate, dimethicone, xanthan gum, peg-100 stearate, allantoin, panthenol, cyclopentasiloxane, fragrance, imidazolidinyl urea, methylparaben, propylparaben, sodium hydroxide.

Package Labeling:1oz

Top/Front



Bottom/Back Adhesive Side



Package Labeling:20z



Bottom/Back Adhesive Side

NO PRINT AREA

- Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days.
 If no discomfart occurs, follow the directions stated below.
- If no discomfort occurs, follow the directions stated below.

 clearse the 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 or three times daily in needed or as directed by a doctor.

 If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

 If going outside, apply sunscreen after using this product.

 If inflation or sensitivity develope, stop use of both products and ask a doctor.

Inactive Ingredients Water, ceteareth-20, propylene glycol, beteeryl alcohol, carbomer, ethoxydiglycol, cyclotetrasiloxane, glyceryl stearate, dimethicone, xarthan gum, peg-100 stearate, aflantoin, parthenol, cyclopentasiloxane, fragrance, imidazoidinyl urse, methylparaben, propylparaben, sodium hydioxide.

SOLIMO REPAIRING TREATMENT FOR ACNE PRONE SKIN

benzoyl peroxide liquid

-					•	c			. •	
μ	ro	a.	116	rt	Ιī	า†ก	m	ma	1111	on

HUMAN OTC DRUG NDC:72288-525 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BENZOYL PEROXIDE (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE - UNII: W9 WZN9 A0 GM) | BENZOYL PEROXIDE | 25 mg in 1 mL

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8 X02B)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALLANTO IN (UNII: 344S277G0Z)	
PANTHENOL (UNII: WV9CM0O67Z)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
IMIDUREA (UNII: M629807ATL)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	

	Packaging						
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	NDC:72288-525-01	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020				
l	NDC:72288-525-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333D	07/30/2020				

Labeler - Amazon.com Services LLC (128990418)

Establishment						
Name	Address	ID/FEI	Business Operations			
Filltech USA, LLC		926433855	manufacture(72288-525)			

Revised: 6/2020 Amazon.com Services LLC