SPOT ON TREATMENT- benzyl peroxide lotion
SGII, 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.

Spot On Treatment

Active Ingredient

Benzoyl Peroxide 10%

Purpose

Acne Treatment

Uses

For the treatment of Acne

Warnings

For External Use Only

Keep Out Of Eyes

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 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

•Clean 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

Allantoin, Aloe Vera (Aloe Barbadensis) Leaf Juice, Bisabolol, Caprylyl Glycol, Carbomer, C13-14 Isoalkane, Diethylhexyl Sodium Sulfosuccinate, Dimethicone, Dimethyl Isosorbide, Ethylhexylglycerin, Ginger (Zingiber Officinale) Root Extract, Hexylene Glycol, Laureth-7, Menthoxypropanediol, Panthenol, PEG-40 Stearate, Phenoxyethanol, Polyacrylamide, Propanediol, Silica, Sodium Citrate, Sodium Hydroxide, Sorbitan Stearate, Water/Aqua/Eau, Xanthan Gum.

SeneGence

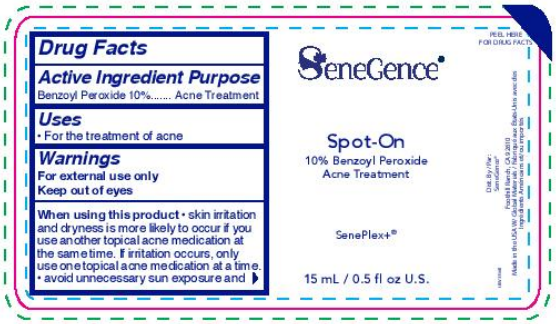
Spot-On

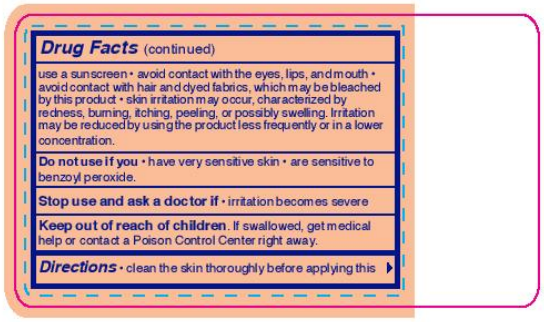
10% Benzoyl Peroxide

Acne Treatment

SenePlex+

15mL/0.5 fl oz U.S.





SPOT ON TREATMENT

benzyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72644-636
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PEG-40 STEARATE (UNII: ECU18C66Q7)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
LAURETH-7 (UNII: Z95S6G8201)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALLANTOIN (UNII: 344S277G0Z)	
LEVOMENOL (UNII: 24WE03BX2T)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
PANTHENOL (UNII: WV9CM0O67Z)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GINGER (UNII: C5529G5JPQ)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72644-636-01	15 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/16/2020	

Labeler - SGII, INC (070096792)

Establishment

Name	Address	ID/FEI	Business Operations
220 LABORATORIES INC		783247950	manufacture(72644-636)

Revised: 12/2021 SGII, INC