SMART RELEASE BPO 10 PERCENT- benzoyl peroxide lotion
SkinClinical AI, 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.

SMART RELEASE BPO 10%

Active ingredients

BENZOYL PEROXIDE 10%

PURPOSE

TREATMENT OF ACNE

USE

For the treatment 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 1 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 or 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 usi ng the product less frequently or in a lower concentration.

Do not use if you have very sensitive skin or sensitive to benzoyl peroxide.

Other information

Keep tightly closed.
Protect from excessive heat (40° / 140° F) and protect from freezing

Stop use and ask a doctor if irritation or sensitivity develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

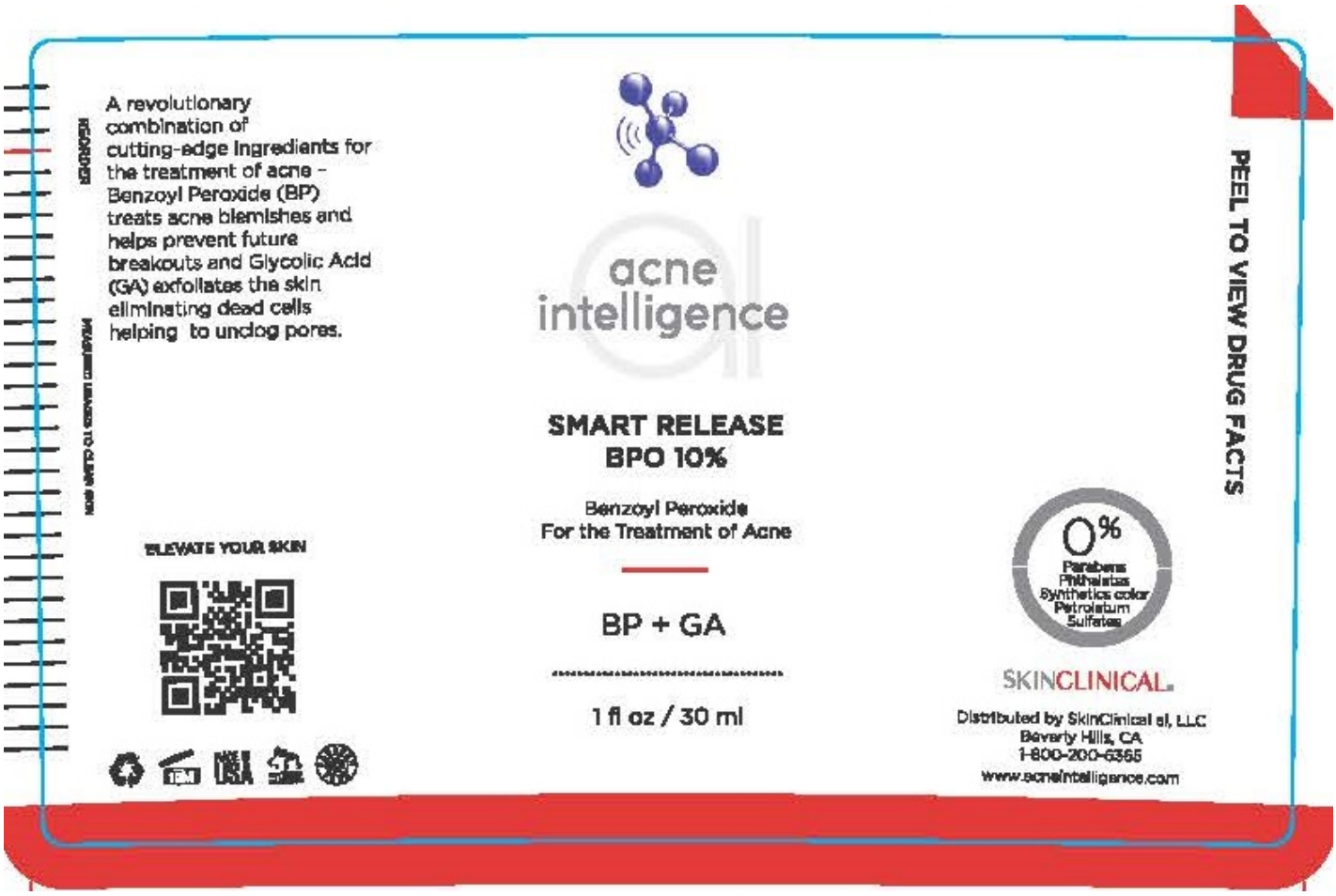
Important to use on a clean face. Cover the affected area with a thin layer 1 to 3 times per day. Because of excessive drying of the skin may occur, start with 1 application per day then gradually increase to 2 applications per day 1 morning and one evening if needed, or as directed by a doctor. If dryness or peeling occurs, reduce use to once a day or once every other day. If going outside, use a sunscreen. If irritation or sensitivity develops stop using both products and ask a doctor.

INACTIVE INGREDIENTS

Water (Aqua), Glycerin, Propylene Glycol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Sulfur, PEG-8 SMDI Copolymer, Lactobacillus Ferment, Glycolic Acid, Lactic Acid, Magnesium Aluminum SIlicate, Citric Acid, Xanthan Gum, Potassium Hydroxide, Phenoxyethanol, Ethylhexylglycerin, Hydrolyzed Algin, Zinc Sulfate, Disodium EDTA, Citrus Aurantium Bergamia (Bergamo!} Fruit Oil, Citrus Grandis (Grapefruit) Peel Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Tangerina (Tangerine) Peel Oil

QUESTIONS?

CALL TOLL-FREE T 1-800-200-6365 OR VISIT WWW.ACNEINTELLIGENCE.COM



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Questions?

Call toll-free T 1-800-200-6365 or visit www.acneintelligence.com

DRUG FACTS

Active Ingredients	***Purpose***
Benzoyl Peroxide 10%	Treatment of Acne

USE: For the treatment of acne.

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SMART RELEASE BPO 10 PERCENT

benzoyl peroxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73110-105
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
PEG-8/SMDI COPOLYMER (UNII: CCX72L6NY6)	
LACTOBACILLUS REUTERI (UNII: 9913I24QEE)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
LACTIC ACID (UNII: 33X04XA5AT)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
ZINC SULFATE (UNII: 89DS0H96TB)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
ORANGE OIL (UNII: AKN3KSD11B)	
TANGERINE PEEL (UNII: JU3D414057)	
SULFUR (UNII: 70FD1KFU70)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73110-105-11	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/16/2019	

Labeler - SkinClinical AI, LLC (116981342)

Registrant - SkinClinical AI, LLC (116981342)

Revised: 9/2019 SkinClinical AI, LLC