

**SMART RELEASE BPO 5 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.*

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**SMART RELEASE BPO 5%**

**PURPOSE**

TREATMENT OF ACNE

**ACTIVE INGREDIENT**

BENZOYL PEROXIDE 5%

**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. 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 OR SENSITIVE TO BENZOYL PEROXIDE.

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

**OTHER INFORMATION**

Keep tightly closed.

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

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 ONE TO THREE TIMES PER DAY. BECAUSE OF EXCESSIVE DRYING OF THE SKIN MAY OCCUR, START WITH ONE APPLICATION PER DAY THEN GRADUALLY INCREASE TO TWO APPLICATIONS PER DAY, ONE 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, 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 (Bergamot) 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.acneintelligencelotion.com](http://www.acneintelligencelotion.com)



**Directions:**  
Important to use on a clean face. Cover the affected area with a thin layer one to three times per day. Because of excessive drying of the skin may occur, start with one application per day then gradually increase to two applications per day, one 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, 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 (Bergamot) 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.acneintelligencelotion.com](http://www.acneintelligencelotion.com)

**DRUG FACTS**

Active Ingredients	Purpose
Benzoyl Peroxide 5%	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 using 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.

## SMART RELEASE BPO 5 PERCENT

benzoyl peroxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73110-102
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS 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: 39W1PKE3JJ)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
ORANGE OIL (UNII: AKN3KSD11B)	
TANGERINE PEEL (UNII: JU3D414057)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73110-102-11	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)