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.

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, ITCHINH, 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

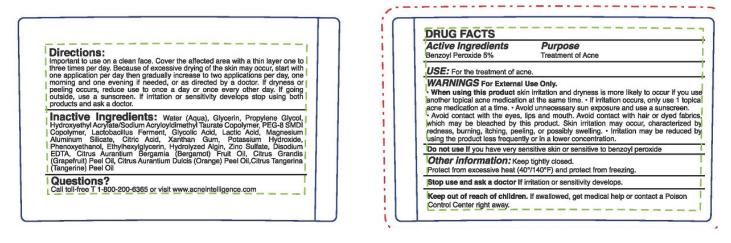
INACTIVE INGREDIENTS

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.acneintellifillnce.com





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		

	In	gredient Name		Basis of St	rength	Strength
BENZOYL PEROX	DE (UNII: W9WZN9	A0GM) (BENZOYL PERO	XIDE - UNII:W9WZN	9A0GM) BENZOYL PE	ROXIDE	5 g in 100 ml
Inactive Ingred	ients					
		Ingredient N	ame			Strengt
WATER (UNII: 0590	F0KO0R)					
GLYCERIN (UNII: P	DC6A3C0OX)					
PROPYLENE GLY	COL (UNII: 6DC9Q	l67V3)				
HYDROXYETHYL 1.5%) (UNII: 86FQE		JM ACRYLO YLDIMETHY	L TAURATE COPO	DLYMER (100000 MP/	A.S AT	
PEG-8/SMDI COPC	LYMER (UNII: CC)	K72L6NY6)				
LACTOBACILLUS	REUTERI (UNII: 99	13I24QEE)				
GLYCOLIC ACID (UNII: 0 WT12SX38S)				
LACTIC ACID (UNI	: 33X04XA5AT)					
MAGNESIUM ALU	INUM SILICATE (UNII: 6 M3P6 4 V0 NC)				
ANHYDRO US CITH	IC ACID (UNII: XF4	17D3PSL)				
XANTHAN GUM (U	NII: TTV12P4NEE)					
PO TASSIUM HYDI	OXIDE (UNII: WZH	3C48M4T)				
PHENO XYETHANO	L (UNII: HIE492ZZ	3T)				
ETHYLHEXYLGLY	CERIN (UNII: 147D2	247K3P)				
SODIUM ALGINAT	E (UNII: C269C4G2	ZQ)				
ZINC SULFATE (U	NII: 89DS0H96TB)					
EDETATE DISODI	M (UNII: 7FLD91C8	86K)				
BERGAMOT OIL (JNII: 39W1PKE3JI)					
GRAPEFRUIT O IL	(UNII: YR377U58W9))				
ORANGE OIL (UN	: AKN3KSD11B)					
TANGERINE PEEL	(UNII: JU3D414057)					
Packaging						
# Item Code	Package Description Mar		Marketing Start Date		ceting End Date	
1 NDC:73110-102- 11	0-102- 30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product 02/16		02/16/2019			
Marketing I	nformation					
Marketing Categ	egory Application Number or Monograph Citation Mar		rketing Start Date	Marketin	ng End Date	
OTC monograph fin	l part333D			02/16/2019		

Labeler - SkinClinical AI, LLC (116981342)