# ANTI BAC ACNE CLEARING- benzoyl peroxide lotion KATE SOMERVILLE SKINCARE, LLC

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KATE SOMERVILLE - ANTI BAC ACNE CLEARING LOTION (43479-105)

#### **ACTIVE INGREDIENT**

**BENZOYL PEROXIDE- 5%** 

### PURPOSE

ACNE TREATMENT

### USE

- FOR THE TREATMENT OF ACNE
- HELPS KEEP SKIN CLEAR OF NEW ACNE BLEMISHES

### WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

- USING OTHER TOPICAL ACNE MEDICATION AT THE SAME TIME OR IMMEDIATELY FOLLOWING THE USE OF THIS PRODUCT MAY INCREASE DRYNESS OR IRRITATION OF THE SKIN. IF THIS OCCURS, ONLY ONE MEDICATION SHOULD BE USED UNLESS DIRECTED BY A DOCTOR.
- DO NOT USE THIS PRODUCT IF YOU HAVE VERY SENSITIVE SKIN OR IF YOU ARE SENSITIVE TO BENZOYL PEROXIDE.
- AVOID UNNECESSARY SUN EXPOSURE AND USE A SUNSCREEN.
- AVOID CONTACT WITH EYES, LIPS, AND MOUTH.
- AVOID CONTACT WITH HAIR AND DYED FABRICS, WHICH MAY BE BLEACHED BY THIS PRODUCT.
- SKIN IRRITATION MY OCCUR, CHARACTERIZED BY REDNESS, BURNING, ITCHING, PEELING, OR POSSIBLE SWELLING. IRRITATION MY BE REDUCED BY USING THE PRODUCT LESS FREQUENTLY OR IN A LOWER CONCENTRATION.

STOP USE AND ASK A DOCTOR IF SKIN IRRITATION BECOMES SEVERE.

KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

## DIRECTIONS

 CLEANSE SKIN THOROUGHLY BEFORE APPLYING. COVER THE AFFECTED AREA WITH A THIN LAYER 1 TO 3 TIMES A DAY. BECAUSE EXCESSIVE DRYING OF THE SKIN MAY OCCUR, START WITH 1 APPLICATION DAILY, THEN GRADUALLY INCREASE TO 2 OR 3 TIMES DAILY IF NEEDED OR AS DIRECTED BY A DOCTOR. IF BOTHERSOME DRYNESS OR PEELING OCCURS, REDUCT 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 PRODUCTS AND ASK A DOCTOR.

## **OTHER INFORMATION**

• YOU MAY REPORT A SERIOUS ADVERSE REACTION FROM USING THIS PRODUCT TO 1-800-984-KATE ON WEEKDAYS 9 A.M.-5 P.M. PT

# **INACTIVE INGREDIENTS**

WATER/AQUA/EAU, PPG-2 MYRISTYL ETHER PROPIONATE, ARGANIA SPINOSA KERNEL EXTRACT, PEG-40 STEARATE, SERENOA SERRULATA FRUIT EXTRACT, SESAMUM INDICUM (SESAME) SEED EXTRACT, ALCOHOL DENAT., SORBITAN STEARATE, HYDROGENATED METHYL ABEITATE, METHYL METHACRYLATE CROSSPOLYMER, CARBOMER, GLYCERYL STEARATE, CETYL ALCOHOL, TETRASODIUM EDTA, HYDROGENATED LECITHIN, CHOLESTEROL, CERAMIDE NS, CERAMIDE NP, OLEIC ACID, PALMITIC ACID, SODIUM ASCORBATE, SODIUM HYDROXIDE, EDTA, ETHYLHEXYLGLYCERIN, PHENOXYETHANOL

#### Anti Bac<sup>Ø</sup> Acne Clearing Lotion Lotion purifiante antibactérienne

Using cutting-edge ingredients, this intensive acrie formula targets pores to help clear edsting blemishes and blackheads.

Contenant des ingrédients de pointe, cette formule intensive contre l'acné agit sur les pores toute la journée pour traiter les imperfections existantes et éliminer les points noirs.

I - 8 0 0 - 9 8 4 - K A T E katesom erville.com MADE IN US A/FABRUGLÉ AUX E-U. This product has not been tested on animals. Ce produit na pas été testé sur des animaux. Distr. Byl par Kate. Somerville.Skincare, LLC Beverty Hills CA 90212. EU Dist. Dist. dars. UE Naritaweg. (65, 1043) BW Amstandam. The Netherlands

## Drug Facts (continued)

may occur, start with I application daily, then gradually increase to 2 or 3 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 initiation or sensitivity develops, stop use of products and ask a doctor.

Inactive Ingredients Water/Aqua/Eau, PPG-2 Myristyl Ether Propionate, Argania Spinosa Kernel Extract, PEG-40 Sterate, Serenoa Serrulata Fruit Extract, Sesamum Indicum (Sesame) Seed Extract, Alcohol Denat., Sorbitan Stearate, Hydrogenated Methyl Abeitate, Methyl Methacrylate Crosspolymer, Carbomer, Glyceryl Stearate, Cetyl Alcohol, Tetrasodium EDTA, Hydrogenated Lecithin, Cholesterol, Ceramide NS, Ceramide NP, Oleic Acid, Palmitic Acid, Sodium Ascorbate, Sodium Hydroxide, EDTA, Ethyhexylglycerin, Phenoxyethanol

Other Information You may report a serious adverse reaction from using this product to 1-800-984-KATE on weekdays 9 a.m.-5 p.m. Pacific Time

> Anti Bac<sup>+</sup> Acne Clearing Lotion Lotion purifiante antibactérienne

Kate

5%

Benzoy

Peroxide

C 50 mL 1.7 Fl. Oz.

#### **Drug Facts**

#### Active Ingredient......Purpose Beraoyl Percoide, 5%... Acre Treatment

#### Use

 For the treatment of acne.
Helps keep skin clear of new acne blemishes.

Warnings

For external use only

- When using this product • Using other topical acne medications at the same time or immediately following use of this product may increase dryness or imitation of the skin. If this occurs, only one medication should be used unless directed by a doctor.
- Do not use this product if you have very sensitive skin or if you are sensitive to Benzoyl Peroxide.
- 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 possible swelling, Irritation may be reduced by using the product less frequently or in a lower concentration.

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

 Cleanse skin thoroughly before applying. Cover the affected area with a thin layer I to 3 times a day. Because excessive drying of the skin

ANTI BAC ACNE CLE	ARING							
benzoyl peroxide lotion								
Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:43479-105				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name			Basis of Strength		Strength			
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)		BENZOYL PE	ROXIDE	5 g in 100 mL				

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
ARGANIA SPINOSA SEED (UNII: 8H7X7XB54H)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
SAW PALMETTO (UNII: J7WWH9M8QS)	
SESAME SEED (UNII: 7Y1255HVXR)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
HYDROGENATED METHYL ABIETATE (UNII: A230709X80)	
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 600000 MW) (UNII: XRK36F13ZZ)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE SODIUM (UNII: MP1J8420LU)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CERAMIDE 2 (UNII: C04977SRJ5)	
CERAMIDE 3 (UNII: 4370DF050B)	
OLEIC ACID (UNII: 2UMI9U37CP)	
PALMITIC ACID (UNII: 2V16EO95H1)	
SODIUM ASCORBATE (UNII: S033EH8359)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETIC ACID (UNII: 9G34HU7RV0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

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#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:43479- 105-52	l in 1 BOX	06/22/2014			
1		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product				
Marketing Information						
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		

Labeler - KATE SOMERVILLE SKINCARE, LLC (615155533)