

PCA SKIN ACNE- benzoyl peroxide cream
CP Skin Health Group, 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.

PCA Skin Acne Cream

ACTIVE INGREDIENT: Benzoyl Peroxide (5.0%)

Purpose: Acne Treatment

USES:

- Treats existing and helps prevent new acne blemishes/blackheads.

WARNINGS:

- When using this product, avoid unnecessary sun exposure and use a sunscreen.
- For external use only
- Using other topical acne drugs 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 drug should be used unless directed by a physician.
- Do not use in or near the eyes.

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

DIRECTIONS: Cleanse skin thoroughly before applying. Apply a small amount of cream to areas where pimples occur. Do not rinse. Start with one acne treatment every other day and gradually increase to once daily or as directed by a physician. **If going outside, use a sunscreen.** Allow Acne Cream to dry, then follow sunscreen label directions. If irritation develops or sensitivity develops, discontinue use of both products and consult a physician.

Other Ingredients: Water/Aqua/Eau, Gluconolactone, Glycerin, Caprylic/Capric Triglyceride, Cetyl Alcohol, Vitis Vinifera (Grape) Seed Oil, Aminomethyl Propanol, Lactic Acid, Aloe Barbadensis Leaf Juice, Cyclopentasiloxane, Dimethicone, Glyceryl Stearate, PEG-100 Stearate, Melaleuca Arternifolia (Tea Tree) Leaf Oil, Tocopheryl Acetate, Ascorbic Acid, Retinyl Palmitate, Anthemis Nobilis Flower Extract, Citrus Grandis (Grapefruit) Peel Oil, Allantoin, Panthenol, Polyacrylate-13, Polyisobutene, Caprylyl Glycol, Ammonium Acryloyldimethyltaurate/VP Copolymer, Potassium Cetyl Phosphate, Ethylhexylglycerin, Hexylene Glycol, Polysorbate 20, Butylene Glycol, Phenoxyethanol.

acne cream

crème pour l'acné

Clear blemishes with this 5% benzoyl peroxide spot treatment including gluconolactone to prevent dryness and irritation. Essential for those with acne.

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© 2016 Physicians Care Alliance, LLC
Scottsdale, AZ 85251 | Made in U.S.A.
Manufactured for Physicians Care Alliance, LLC
21174



net wt 0.5 oz/14.2 g

Drug Facts

Active Ingredient

Purpose

Derzoyl Peroxide (5.0%)

Acne Treatment

Uses

For the treatment of acne. Helps keep skin clear of new acne pimples, blackheads and/or whiteheads.

Warnings

For external use only.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

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.

Drug Facts (continued)

Warnings (continued)

Stop use and ask a doctor if skin 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.

Questions?

Please call 877.722.7546

PCA SKIN ACNE

benzoyl peroxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68726-169
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 g
Inactive Ingredients			
Ingredient Name			Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
ALLANTOIN (UNII: 344S277G0Z)			

PANTHENOL (UNII: W9CM0067Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GRAPE (UNII: 6X543N684K)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
LACTIC ACID (UNII: 33X04XA5AT)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
TEA TREE OIL (UNII: VIF565UC2G)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68726-169-04	1 in 1 CARTON	04/01/2010	
1	NDC:68726-169-01	14 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:68726-169-02	7 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2010	08/31/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	04/01/2010	

Labeler - CP Skin Health Group, Inc. (611921669)