

**JON ARES ACNE CONTROL STEP 1- benzoyl peroxide cream
DADASHIE ACNE SYSTEM 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.

JON ARES (as PLD) - ACNE CONTROL CREAM - STEP 1 (71748-101)

ACTIVE INGREDIENTS

BENZOYL PEROXIDE 5%

PURPOSE

ACNE TREATMENT

USE:

FOR THE TREATMENT OF ACNE

DIRECTIONS:

- CLEANSE THE SKIN THOROUGHLY BEFORE APPLYING THIS PRODUCT.
- COVER THE ENTIRE AFFECTED AREA WITH A THIN LAYER ONE TO THREE TIMES DAILY. BECAUSE OF EXCESS 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 PHYSICIAN.
- IF BOTHERSOME DRYNESS, REDNESS, ITCHING OR PEELING OCCURS, REDUCE APPLICATION TO ONCE A DAY OR EVERY OTHER DAY. STOP USE AND ASK A PHYSICIAN IF IRRITATION BECOMES SEVERE.
- IF GOING OUTSIDE, APPLY SUNSCREEN AFTER USING THIS PRODUCT. IF IRRITATION OR SENSITIVITY DEVELOPS, STOP USE OF BOTH PRODUCTS AND ASK A PHYSICIAN.

WARNINGS:

FOR EXTERNAL USE ONLY.

DO NOT USE THIS PRODUCT IF YOU HAVE VERY SENSITIVE SKIN OR IF YOU ARE SENSITIVE TO BENZOYL PEROXIDE. THIS PRODUCT MAY CAUSE IRRITATION.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE USING OTHER TOPICAL ACNE MEDICATIONS AT THE SAME TIME OR IMMEDIATELY FOLLOWING USE OF THIS PRODUCT. THIS MAY INCREASE DRYNESS OR IRRITATION OF THE SKIN. IF THIS OCCURS, ONLY ONE MEDICATION SHOULD BE USED UNLESS DIRECTED BY A DOCTOR. AVOID UNNECESSARY SUN EXPOSURE. USE A SUNSCREEN, WHILE USING THIS PRODUCT AND FOR A WEEK AFTERWARDS.

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

KEEP OUT OF REACH OF CHILDREN. KEEP AWAY FROM LIPS AND MOUTH. IF SWALLOWED, GET MEDICAL HELP OR CONTACT THE POISON CONTROL CENTER RIGHT AWAY.

OTHER INFORMATION.

THIS PRODUCT MAY BLEACH HAIR OR DYE FABRICS. AVOID STORING AT EXTREME TEMPERATURES (BELOW 40°F AND ABOVE 100°F).

INACTIVE INGREDIENTS:

WATER, PROPYLENE GLYCOL, POLYACRYLAMIDE, C13-14 ISOPARAFFIN, LAURETH-7, BENZYL ALCOHOL, CAPRYLHYDROXIC ACID, GLYCERIN.



Acne Control Cream Step 1

Drug Facts	
Active Ingredient	Purpose
Benzoyl Peroxide 5%.....	Acne Treatment
■ USE: For the treatment of acne	
Warnings <ul style="list-style-type: none"> ■ For external use only. ■ Avoid contact with the eyes, lips and mouth. ■ Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a poison control center right away. ■ Do not use on children under 2 years of age unless directed by a doctor. ■ Do not use if you have very sensitive skin or sensitive to Benzoyl Peroxide 	
When using this product <ul style="list-style-type: none"> ■ 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 hair and dyed fabrics, which may be bleached by this product. 	
Directions <ul style="list-style-type: none"> ■ Clean the skin thoroughly before applying this product. ■ Cover the entire affected area with a thin layer one to three times daily. Because of excess 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 physician. ■ If bothersome dryness, redness, itching or peeling occurs, reduce application to once a day or every other day. Stop use and ask a physician if irritation becomes severe. ■ If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a physician. 	
Other Information. This product may bleach hair or dry fabrics. avoid storing at extreme temperatures (below 40°F and above 100°F)	
Inactive Ingredients Water, Propylene Glycol, Polyacrylamide, C 13-14 Isoparaffin, Laureth -7, Benzyl Alcohol, Caprylhydroxamic Acid, Glycerin.	

Manufactured for: Dermatix Acne Systems Inc. Anaheim, CA 92805. 800-300-ACNE (2263) Made in USA

JON ARES ACNE CONTROL STEP 1			
benzoyl peroxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71748-101

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: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRW)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71748-101-11	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	09/30/2017	

Labeler - DADASHIE ACNE SYSTEM INC (032214636)

Revised: 8/2023

DADASHIE ACNE SYSTEM INC