JON ARES ACNE CONTROL STEP 2- 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 2 (71748-102)

ACTIVE INGREDIENTS

BENZOYL PEROXIDE 10%

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.
- AVOID CONTACT WITH THE EYES, LIPS, AND MOUTH.

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 UNECESSARY SUN EXPOSURE AND USE SUNSCREEN.
- AVOID CONTACT WITH HAIR AND DYED FBRICS, WHICH MAY BE BLEACHED BY THIS PRODUCT.

- KEEP THIS AND ALL DRUGS OUT OF 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.

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



Acne Control Cream

Step 2

Eliminates Bacteria Prevents Breakouts

JON ARES

2 fl oz (60 mL)

Drug Facts Active ingredient Benzoyl Percodde 10% Acna Treatment II USE: For the treatment of news For external use only. Avoid contact with the eyes, lips and mouth. II Keep this cant all drays out of the reach of children. If a get medical help or contact a poison control contac right energ. Be mak use on children under 2 years of age unless directed by a doctor. the mail was if you have very sensitive skin or sensitive to Banzoyl Perceide When using this product Sidn irritation and dryness is more likely to occur if you use another topical acre medication at the same time. If irritation occurs, only use one toolcal acre 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 Clean the sidn 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 sidn may occur, start with one application daily, then gradually increase to two or firee 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. Step use and usk a physicina il britalica becomes severe. III If going outside, apply surscreen 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)

Water, Suffur, Propylene Stycol, Polyacrylemide, C 13-14 isoparatifin, Laureth --7, Benzyl Alcohol, Caprythydroxamic Acid, Glycerin.

Hieraphetured for : Dadonhila Acne Systems Inc. Anaheira, CA 82805, 889-100 ACHE (2283) Neels in USA

Acne Control Cream Step 2

bactive ingredients

JON ARES ACNE CONTROL STEP 2

benzoyl peroxide cream

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71748-102 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | |
|---|----------------------|-------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII: W9WZN9A0GM) | BENZOYL PEROXIDE | 10 g in 100 mL | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| WATER (UNII: 059QF0KO0R) | | | |
| SULFUR (UNII: 70FD1KFU70) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) | | | |
| LAURETH-7 (UNII: Z95S6G8201) | | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |

| l | P | Packaging | | | | |
|---|---|----------------------|--|-------------------------|-----------------------|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | 1 | NDC:71748-102- 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 | | |
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Labeler - DADASHIE ACNE SYSTEM INC (032214636)

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