

JON ARES ACNE CONTROL MILD- resorcinil, sulfur 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 - MILD (71748-103)

ACTIVE INGREDIENTS

RESORCINOL 2%

SULFUR 6%

PURPOSE

ACNE TREATMENT

USE:

FOR THE TREATMENT OF ACNE

DIRECTIONS:

- CLEANSE THE SKIN THOROUGHLY BEFORE APPLYING THIS PRODUCT.
- PCOVER 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 IFFITATION 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.

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

- 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 A SUNSCREEN.
- AVOID CONTACT WITH HAIR AND DYED FABRICS, WHICH MAY BE BLEACHED BY THIS PRODUCT.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A 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, C 13-14 ISOPARAFFIN, LAURETH-7, BENZYL ALCOHOL, CAPRYLHYDROXAMIC ACID, GLYCERIN, ZINC OXIDE.



Acne Control Cream Mild

Drug Facts	
Active Ingredients	Purpose
Resorcinol 2%.....	Acne Treatment
Sulfur 6%.....	Acne Treatment
■ USE : For the treatment of acne	
Warnings	
■ 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	
■ 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	
■ 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, Zinc Oxide.	

Manufactured for : DataLab Acne Systems Inc. Anaheim, CA 92608. 800-300 ACNE (2263) Made in USA

resorcinil, sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71748-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	2 g in 100 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWW)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
GLYCERIN (UNII: PDC6A3C0OX)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71748-103-11	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)