O SKIN ACNE MODERATE- benzoyl peroxide cream O SKIN CARE LLC

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.

O SKIN - ACNE CREAM MODERATE (71421-101)

ACTIVE INGREDIENTS

BENZOYL PEROXIDE 5%

PURPOSE

ACNE TREATMENT

USE:

FOR THE TREATMENT OF ACNE

DIRECTIONS:

CLEANSE THE SKIN THOROUGHLY BEFORE APPLYING THIS PRODUCT. PAT A THIN LAYER TO AFFECTED AREA DAILY MORNING AND NIGHT AND ALLOW TO DRY.

- BECAUSE EXCESSIVE DRYING MAY OCCUR, START WITH ONCE DAILY APPLICATION.
- IF BOTHERSOME DRYNESS OR PEELING OCCURS, REDUCE APPLICATION TO EVERY OTHER DAY.

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 PHYSICIAN 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 PHYSICIAN. AVOID UNNECESSARY SUN EXPOSURE. USE A SUNSCREEN WHILE USING THIS PRODUCT AND FOR A WEEK AFTERWARDS.

STOP USE AND ASK A PHYSICIAN 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:

DEIONIZED WATER, PROPYLENE GLYCOL, POLYACRYLAMIDE, C13-14 ISOPARAFFIN, LAURETH-7, BENZYL ALCOHOL, CAPRYLHYDROXAMIC ACID, GLYCRIN





Acne Cream Moderate

| Drug Facts | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Active Ingredient | Purpose |
| Benzoyl Peroxide 5% | Acne Treatment |
| Use: For the treatment | of acne. |
| Pat a thin layer to affected area 1 Morning and night. Allow to dry. Because excessive drying may | |
| Warnings: For external use | e only |
| Do not use this product if yo sensitive skin or if you are sensit Benzoyl Peroxide, This product r | tive to |
| topical acne medications at the san following use of this product. This irritation of the skin. If this occurs, be used unless directed by a docto exposure. Use a sunscreen, wh week afterwards. | may increase dryness or only one medication should r. Avoid unnecessary sun ille using this product and for a at avoid contact with eyes. If contact |
| Stop use and ask doctor | if skin irritation occurs, and becomes severe |
| | ren_ Keep away from lips and mouth, contact a Poison Control Center right away. |
| Other Information. This phair or dye fabrics. Avoid storin temperatures (below 40 °F and a | ng at extreme |
| | |

O SKIN CARE
Manufactured exclusively for
Olivia Quido
Los Angeles, CA 90041
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Inactive Ingredients: Water, Propylene Glycol, Polyacrylamide, C 13-14 Isoparaffin, Laureth—7, Benzyl Alcohol, Caprylhydroxamic Acid, Glycerin.







2 Fl. Oz. | 60 ml

O SKIN ACNE MODERATE

benzoyl peroxide cream

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71421-101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------------------|----------------------|------------------|
| BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZ OYL PEROXIDE - UNII: W9WZ N9A0GM) | BENZOYL PEROXIDE | 5 g in 100 mL |

| Inactive Ingredients | | |
|----------------------------------------------|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I) | | |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) | | |
| LAURETH-7 (UNII: Z95S6G8201) | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |

| P | Packaging | | | |
|---|----------------------|------------------------------------------------------|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71421-101- 11 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/12/2017 | |

| Marketing Information | | | |
|-----------------------|---------------------------------------------|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part333D | 05/01/2017 | |
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Labeler - O SKIN CARE LLC (021275401)

Registrant - O SKIN CARE LLC (021275401)

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