

ACNE CONTROL CLEANSER - benzoyl peroxide cream
DOLGENCORP 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.

DRUG FACTS

ACTIVE INGREDIENT

BENZOYL PEROXIDE 10%

PURPOSE

ACNE TREATMENT

USES

FOR THE TREATMENT OF ACNE.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THE PRODUCT

- SKIN IRRITATION AND DRYNESS IS MORE LIKELY TO OCCUR IF YOU USE ANOTHER TOPICAL ACNE MEDICATION AT THE SAME TIME.
- AVOID UNNECESSARY SUN EXPOSURE AND USE A SUNSCREEN
- AVOID CONTACT WITH EYES, LIPS AND MOUTH.
- AVOID CONTACT WITH HAIR OR 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.

STOP USING THIS PRODUCT AND ASK DOCTOR IF IRRITATION OR REDNESS BECOMES SEVERE.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY. AVOID CONTACT WITH EYES. IF CONTACT OCCURS FLUSH THOROUGHLY WITH WATER.

DIRECTIONS

- WET FACE. GENTLY MASSAGE ALL OVER FACE FOR 20-30 SECONDS AVOIDING EYE AREA. RINSE THOROUGHLY AND PAT DRY.
- SINCE EXCESSIVE DRYNES OF SKIN MAY OCCUR, START WITH ONE APPLICATION DAILY AND INCREASE TO TWO TIMES A DAY IF NEEDED OR 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 USING BOTH PRODUCTS AND ASK A DOCTOR.

OTHER INFORMATION

KEEP TIGHTLY CLOSED. AVOID STORING AT TEMPERATURES ABOVE 90 DEGREES FAHRENHEIT.

QUESTIONS OR COMMENTS

1-888-309-9030

INACTIVE INGREDIENTS

GLYCERIN, PETROLATUM, WATER, SODIUM C12-15 ALKYL BENZOATE, MINERAL OIL, SODIUM COCOYL ISETHIONATE, ZINC LACTATE, SODIUM C14-16 OLEFIN SULFONATE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, POTASSIUM POLYPHOSPHATE, MENTHOL, FRAGRANCE, TITANIUM DIOXIDE, CARBOMER, TRIETHANOLAMINE.

Front and back labels

Drug Facts

Active ingredient Benzoyl Peroxide (10%) **Purpose** Acne treatment

Uses ■ For the treatment of acne

Warnings

■ **For external use only.**

When using this product ■ Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. ■ avoid unnecessary sun exposure and use a sunscreen ■ avoid contact with eyes, lips and mouth. ■ avoid contact with hair or 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.

Do not use if you ■ have very sensitive skin ■ are sensitive to benzoyl peroxide.

Stop using this product and ask doctor if ■ irritation or redness becomes severe

Keep out of reach of children ■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately. Avoid contact with eyes. If contact occurs flush thoroughly with water.

Directions ■ Wet face. Gently massage all over face for 20-30 seconds avoiding eye area. Rinse thoroughly and pat dry. ■ Since excessive dryness of skin may occur, start with one application daily and increase to two times a day if needed or 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 using both products and ask a doctor.

Other information: Keep tightly closed. Avoid storing at temperatures above 90°F

Questions/comments? 1-888-309-9030

Inactive ingredients: Glycerin, Petrolatum, Water (Aqua), Sodium C12-15 Alkyl Benzoate, Mineral Oil, Sodium Cocoyl Isethionate, Zinc Lactate, Sodium C14-16 Olefin Sulfonate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Potassium Polyphosphate, Menthol, Fragrance (Parfum), Titanium Dioxide, Carbomer, Triethanolamine.

*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Clean & Clear®, 12-10381

**100%
Quality
Guaranteed**
(888) 309-9030

DISTRIBUTED BY
DOLGENCORP, LLC
100 WEST 10TH STREET



Acne Control Cleanser

- For daily use
- Cleanser for acne prone skin
- Helps fight against blemishes

Compare to Clean & Clear®
Continuous Control® Acne Cleanser*

ACNE CONTROL CLEANSER

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-825
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 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

PETROLATUM (UNII: 4T6H12BN9U)
WATER (UNII: 059QF0KO0R)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
MINERAL OIL (UNII: T5L8T28FGP)
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)
ZINC LACTATE (UNII: 2GXR25858Y)
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)
POTASSIUM METAPHOSPHATE (UNII: 01DMT14Z63)
MENTHOL (UNII: L7T10EIP3A)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CARBOMER 934 (UNII: Z135WT9208)
TROLAMINE (UNII: 9O3K93S3TK)
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-825-05	141 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	10/25/2011	

Labeler - DOLGENCORP INC (068331990)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture