

PANOXYL- benzoyl peroxide cream
Crown Laboratories

Panoxyl Acne Foaming Wash

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

Use

- for the treatment of acne

Warnings

For external use only

Do not use if you

- have very sensitive skin
- are 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 the eyes, lips and mouth
- avoid contact with hair and 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 use and ask a doctor if

- irritation becomes severe

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet area to be cleansed
- apply acne wash and gently massage area for 1-2 minutes
- rinse thoroughly and pat dry
- because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 times daily if needed or as 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 use of both products and ask a doctor.

Other information

- Store at 20 ° - 25 °C (68 ° - 77 °F) [see USP Controlled Room Temperature].

Inactive ingredients

carbomer homopolymer type C, carbomer interpolymer type A, decyl glucoside, dimethicone, dioctyl sodium sulfosuccinate, glycerin, palmitic acid, polyacrylate crosspolymer-6, polyoxyl 40 stearate, propanediol, purified water, silica, sodium chloride, sodium citrate, sodium hydroxide, sodium laurylglucosides hydroxypropylsulfonate, sorbitan stearate, sorbitol, stearic acid, t-butyl alcohol, xanthan gum

Questions or comments?

call **1-833-279-6522**

Panoxyl 10% Tube

NDC 0316-0228-55

DERMATOLOGIST RECOMMENDED

PanOxyl®

ACNE FOAMING WASH

10% Benzoyl Peroxide

Maximum Strength

Clears Existing Acne and Helps Prevent New Breakouts from Forming

Treats Acne on Face and Body

Maximum Strength without a Prescription

Net wt. 5.5oz (156g)

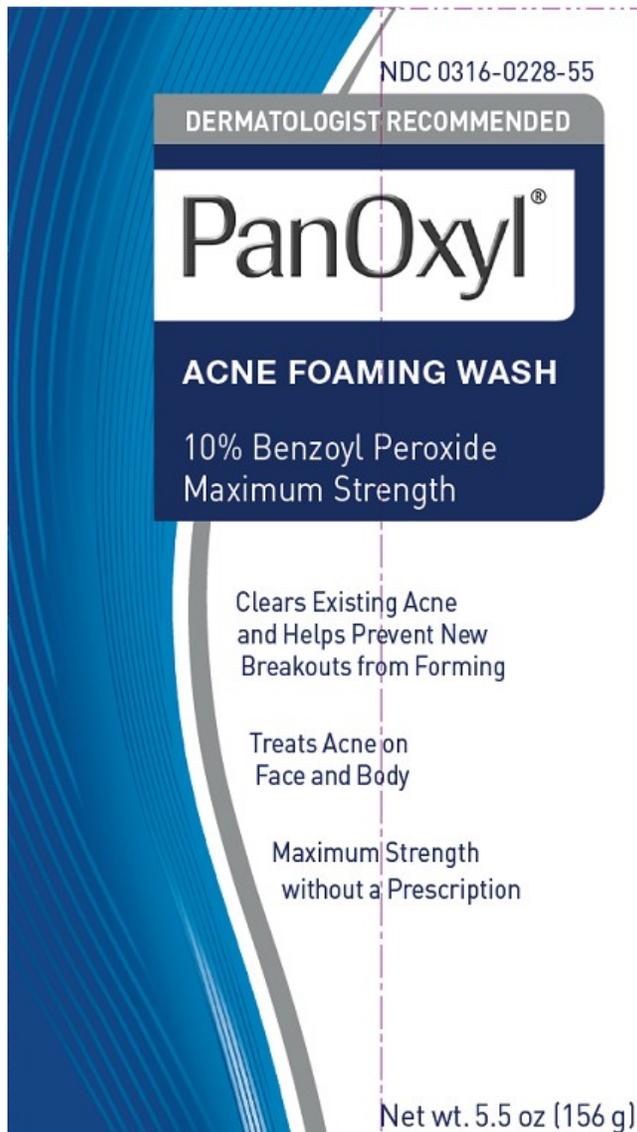
TAMPER-EVIDENT FEATURE:

For your protection, do not use if foil seal on tube is broken or missing.

P11536.03

PANOXYL is a registered trademark of Crown Laboratories, Inc.

Distributed by: Crown Laboratories, Inc. Johnson City, TN 37604



| | | |
|---|--|-----------------------------------|
| TAMPER-EVIDENT FEATURE: For your protection, do not use if foil seal on tube is broken or missing. | | P11536.03 |
| Drug Facts | | |
| Active ingredient Benzoyl peroxide 10%..... | | Purpose Acne medication |
| Use • for the treatment of acne | | |
| Warnings For external use only | | |
| Do not use if you • have very sensitive skin • are 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 the eyes, lips and mouth • avoid contact with hair and 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 use and ask a doctor if • irritation becomes severe | | |
| If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | | |
| Directions • wet area to be cleansed • apply acne wash and gently massage area for 1-2 minutes • rinse thoroughly and pat dry • because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 times daily if needed or as 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 use of both products and ask a doctor. | | |
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Panoxyl 10% Carton

NDC 0316-0228-55

DERMATOLOGIST RECOMMENDED

PanOxyl®

ACNE FOAMING WASH

10% Benzoyl Peroxide

Acne Treatment Wash

Maximum Strength

Clears Existing Acne and Helps Prevent New Breakouts from Forming

Treats Acne on Face and Body

Maximum Strength without a Prescription

Net wt. 5.5oz (156g)

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P11731.03

PanOxyl® Acne Foaming Wash contains maximum strength benzoyl peroxide to clear tough breakouts. PanOxyl treats acne by cleaning and unclogging pores.



| Drug Facts | |
|---|-----------------|
| Active ingredient | Purpose |
| Benzoyl peroxide 10% | Acne medication |
| Use | |
| • for the treatment of acne | |
| Warnings | |
| For external use only | |
| Do not use if you | |
| • have very sensitive skin | |
| • are 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. | |
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| • 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 use and ask a doctor if | |
| • irritation becomes severe | |
| If pregnant or breast-feeding, ask a health professional before use. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions | |
| • wet area to be cleansed | |
| • apply acne wash and gently massage area for 1–2 minutes | |
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NDC 0316-0228-55

DERMATOLOGIST RECOMMENDED

PanOxyl®

ACNE FOAMING WASH

10% Benzoyl Peroxide
Acne Treatment Wash
Maximum Strength



Clears Existing Acne
and Helps Prevent New
Breakouts from Forming

Treats Acne on
Face and Body

Maximum Strength
without a Prescription



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P11731.03

Net wt. 5.5 oz [156 g]

PANOXYL

benzoyl peroxide cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0316-0228 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM) | BENZOYL PEROXIDE | 100 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) | |
| PALMITIC ACID (UNII: 2V16EO95H1) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I) | |
| PROPANEDIOL (UNII: 5965N8WB5T) | |
| SODIUM LAURYLGLUCOSIDES HYDROXYPROPYLSULFONATE (UNII: Z6GFR7R72Y) | |
| TERT-BUTYL ALCOHOL (UNII: MD83SFE959) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0316-0228-01 | 1 in 1 CARTON | 10/12/2022 | |
| 1 | | 28 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:0316-0228-03 | 85 g in 1 TUBE; Type 0: Not a Combination Product | 11/12/2022 | |
| 3 | NDC:0316-0228-55 | 1 in 1 CARTON | 12/01/2018 | |
| 3 | | 156 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M006 | 03/25/2011 | |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| Crown Laboratories | | 079035945 | manufacture(0316-0228) |

Revised: 4/2024

Crown Laboratories