

BENZOYL PEROXIDE- benzoyl peroxide liquid
Burel Pharmaceuticals, LLC

BENZOYL PEROXIDE TOPICAL WASH

DRUG FACTS

Active Ingredient

benzoyl peroxide USP, 5% or 10%

Purpose

Acne medication

Use

- For the treatment of acne

Warnings:

For external use only.

- Avoid contact with eyes, eyelids, lips and mucous membranes.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

When using this product

- **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.
- 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.
- **Stop use and ask a doctor if irritation becomes severe.**

Keep out of reach of children

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

Directions

SHAKE WELL.

- Clean the skin thoroughly before applying this product.
- **Sensitivity Test for a New User.** Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- One to three times daily, wet skin and cover the entire affected area with a thin layer, liberally applying to areas to be cleansed. Massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry.
- Because excessive 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 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.**
- Follow directions in the sunscreen labeling.
- If irritation or sensitivity develops stop use of both products and ask a doctor.

Other information

Store at controlled room temperature, 15° - 30°C (59° - 86°F)

Inactive Ingredients

Carbomer interpolymers type A NF, cetyl alcohol NF, disodium oleamide MEA-sulfosuccinate, edetate disodium USP, glycerin USP, glyceryl stearate/PEG-100 stearate, laureth-12, magnesium aluminum silicate NF, propylene glycol USP, purified water USP, sodium coco-sulfate, sodium lauroamphoacetate, and xanthan gum NF.

Questions? Call 1-866-525-0688

Manufactured for:

Burel Pharmaceuticals, LLC

Mason, OH 45040 USA

LA-45408

Rev. 01/22

PRINCIPAL DISPLAY PANEL - 5% 5oz (148 g) Bottle Label

NDC 35573-453-91

**BENZOYL
PEROXIDE
TOPICAL
WASH 5%**

FOR TOPICAL USE ONLY

Net Weight 5 oz

(148 g)

burelpharma

DRUG FACTS	
Active Ingredient 5% benzoyl peroxide USP....	Purpose Acne medication
Use ■ For the treatment of acne	
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Do not use if you ■ have very sensitive skin ■ are sensitive to benzoyl peroxide	
When using this product ■ 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. ■ 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. ■ Stop use and ask a doctor if irritation becomes severe.	
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Questions? Call 1-866-525-0688.	
Manufactured for: Burel Pharmaceuticals, LLC Mason, OH 45040 USA	
LA-45391	Rev. 01/22
NDC 35573-453-91	
BENZOYL PEROXIDE TOPICAL WASH 5%	
FOR TOPICAL USE ONLY	
Net Weight 5 oz (148 g)	

PRINCIPAL DISPLAY PANEL - 5% 8oz (237 g) Bottle Label

NDC 35573-453-08

**BENZOYL
PEROXIDE
TOPICAL
WASH 5%**

FOR TOPICAL USE ONLY

**Net Weight 8 oz
(237 g)**

burelpharma

DRUG FACTS

Active Ingredient **Purpose**
5% benzoyl peroxide USP.....Acne medication

Use

- For the treatment of acne

Warnings: For external use only.

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Drug Facts (continued)

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Questions? Call 1-866-525-0688.

Manufactured for:
Burel Pharmaceuticals, LLC
Mason, OH 45040 USA

LA-45308
Rev. 01/22



NDC 35573-453-08

BENZOYL PEROXIDE TOPICAL WASH 5%

FOR TOPICAL USE ONLY



Net Weight 8 oz
(237 g)

burelpharma

PRINCIPAL DISPLAY PANEL - 10% 5oz (148 g) Bottle Label

NDC 35573-454-91

**BENZOYL
PEROXIDE
TOPICAL
WASH 10%**

FOR TOPICAL USE ONLY

**Net Weight 5 oz
(148 g)**

burelpharma

DRUG FACTS

Active Ingredient 10% benzoyl peroxide USP ... **Purpose** Acne medication

Use

- For the treatment of acne

Warnings: For external use only.

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Do not use if you

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When using this product

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Questions? Call 1-866-525-0688.

Manufactured for:
Burel Pharmaceuticals, LLC
Mason, OH 45040 USA

LA-45491

Rev. 01/22



NDC 35573-454-91

BENZOYL PEROXIDE TOPICAL WASH 10%

FOR TOPICAL USE ONLY



Net Weight 5 oz
(148 g)

burelpharma

PRINCIPAL DISPLAY PANEL - 10% 8oz (237 g) Bottle Label

NDC 35573-454-08

**BENZOYL
PEROXIDE
TOPICAL
WASH 10%**

FOR TOPICAL USE ONLY

**Net Weight 8 oz
(237 g)**

burelpharma

DRUG FACTS

Active Ingredient **Purpose**
10% benzoyl peroxide USP... Acne medication

Use

- For the treatment of acne

Warnings: For external use only.

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Do not use if you

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When using this product

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Questions? Call 1-866-525-0688.

Manufactured for:
Burel Pharmaceuticals, LLC
Mason, OH 45040 USA

LA-45408
Rev. 01/22



NDC 35573-454-08

BENZOYL PEROXIDE TOPICAL WASH 10%

FOR TOPICAL USE ONLY



Net Weight 8 oz
(237 g)

burelpharma

BENZOYL PEROXIDE

benzoyl peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35573-453
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZ9A0GM) (Benzoyl Peroxide - UNII:W9WZ9A0GM)	Benzoyl Peroxide	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
cetyl alcohol (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
edetate disodium (UNII: 7FLD91C86K)	

glycerin (UNII: PDC6A3C00X)	
laureth-12 (UNII: OAH19558U1)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium coco-sulfate (UNII: 3599J29ANH)	
sodium lauroamphoacetate (UNII: SLK428451L)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	white (viscous)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35573-453-91	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2022	
2	NDC:35573-453-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	04/15/2022	

BENZOYL PEROXIDE

benzoyl peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35573-454
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
cetyl alcohol (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
edetate disodium (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C00X)	
laureth-12 (UNII: OAH19558U1)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0K00R)	
sodium coco-sulfate (UNII: 3599J29ANH)	
sodium lauroamphoacetate (UNII: SLK428451L)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	white (viscous)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

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1	NDC:35573-454-91	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2022	
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OTC Monograph Drug	M006	04/15/2022	

Labeler - Burel Pharmaceuticals, LLC (609436204)

Establishment

Name	Address	ID/FEI	Business Operations
Groupe PARIMA Inc.		252437850	label(35573-453, 35573-454) , manufacture(35573-453, 35573-454) , pack(35573-453, 35573-454)

Revised: 1/2022

Burel Pharmaceuticals, LLC