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 interpolymer type A NF, cetyl alcohol NF, disodium oleamido MEAsulfosuccinate, 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



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



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

Purpose Active Ingredient 10% benzoyl peroxide USP.... 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,
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- 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.

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

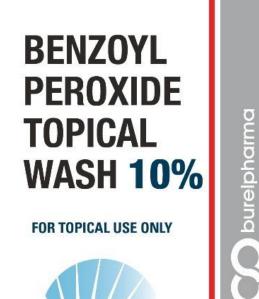
Inactive Ingredients Carbomer interpolymer type A NF, cetyl alcohol NF, disodium oleamido MEAsulfosuccinate, edetate disodium USP, glycerin USP, glyceryl stearate/PEG-100 stearate, laureth-12, magnesium aluminum silicate NF, propylene glycol USP, purified water USP, sodium coco-sulfate, sodium auroamphoacetate, and xanthan gum NF.

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Questions? Call 1-866-525-0688. Manufactured for:

Mason, OH 45040 USA





NDC 35573-454-91

Net Weight 5 oz (148 g)

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

Do not use if you

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Directions: SHAKE WELL.

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Drug Facts (continued)

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

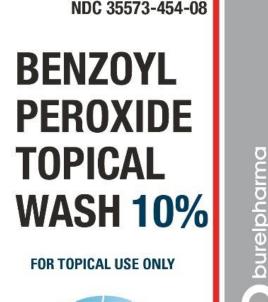
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Questions? Call 1-866-525-0688.

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

LA-45408 Rev. 01/22





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Net Weight 8 oz (237 g)

BENZOYL PEROXIDE benzoyl peroxide liquid **Product Information** HUMAN OTC DRUG Item Code (Source) NDC:35573-453 **Product Type Route of Administration** TOPICAL Active Ingredient/Active Moiety **Basis of Ingredient Name** Strength Strength Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide -50 mg **Benzoyl Peroxide** UNII: W9WZ N9A0GM) in 1 mL Inactive Ingredients **Ingredient Name** Strength cetyl alcohol (UNII: 936JST6JCN) DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)

edetate disodium (UNII: 7FLD91C86K)

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Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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		35573-454	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Active ingredient/Active Projecty					
Ingre		Basis of Strength		Strength	
Benzoyl Peroxide (UNII: W9WZN9 UNII:W9WZN9A0GM)	A0GM) (Benzoyl Peroxide -		Benzoyl Peroxide	e	100 mg in 1 mL
Inactive Ingredients					

	Ingredient Name				
cetyl alcohol (UNII: 936JST6JCN)					
	IDO MON	OETHANOLAMINE SULFOSUCCINA	FE (UNII: 5M1101WGSY)		
edetate disodium	(UNII: 7FL	D91C86K)			
glycerin (UNII: PDC)	6A3C0OX)				
laureth-12 (UNII: O	AH19558L	J1)			
magnesium alumi	num silic	ate (UNII: 6M3P64V0NC)			
propylene glycol (UNII: 6DC	9Q167V3)			
water (UNII: 059QF0K00R)					
sodium coco-sulfa	ate (UNII:	3599J29ANH)			
sodium lauroamphoacetate (UNII: SLK428451L)					
xanthan gum (UNII	: TTV12P4	NEE)			
Product Chara	icterist	ics			
Color		white (viscous)	Score		
Shape			Size		
Flavor			Imprint Code		
Contains					
Packaging					
			Marketing Start	Marketing E	
# Item Code		Package Description	Date	Date	
 # Item Code NDC:35573-454- 	148 mL ir Product	Package Description	Date		
 # Item Code 1 NDC:35573-454- 91 2 NDC:35573-454- 	Product		Date 04/15/2022		
 # Item Code 1 NDC:35573-454- 91 2 NDC:35573-454- 	Product 237 mL ir	n 1 BOTTLE; Type 0: Not a Combinatio	Date n 04/15/2022		

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

Labeler - Burel Pharmaceuticals, LLC (60943620)4)
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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