MEDPURA BENZOYL PEROXIDE AQUEOUS BASE, ACNE TREATMENT GEL- benzoyl peroxide gel
Akron Pharma 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.

MEDPURA 5% and 10% Benzoyl Peroxide Aqueous Base, Acne Treatment Gel

Drug Facts

Active ingredient

Benzoyl peroxide 5%

Benzoyl peroxide 10%

Purpose

Acne treatment

Use

for the treatment of acne

Warnings

For external use only

Do not use this medication if you have very sensitive skin or if you 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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- **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.**
- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily
- 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. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

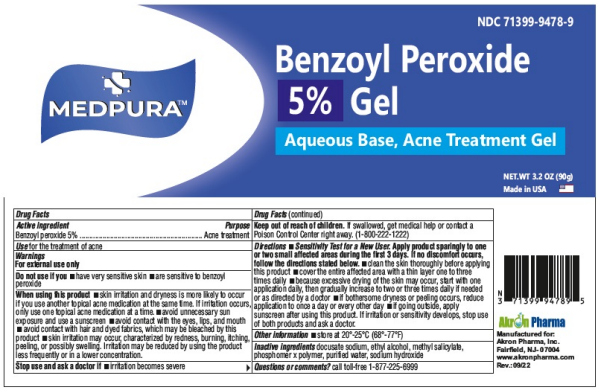
docusate sodium, ethyl alcohol, methyl salicylate, phosphomer x polymer, purified water, sodium hydroxide

Questions or comments?

call toll-free 1-877-225-6999

Manufactured for:

Akron Pharma, Inc.
Fairfield, NJ-07004
www.akronpharma.com



NDC 71399-9478-9

MEDPURA™

Benzoyl Peroxide 5% Gel

Aqueous Base, Acne Treatment Gel

NET.WT 3.2 OZ (90g)

Made in USA

Drug Facts

Active Ingredient	Purpose
Benzoyl peroxide 5%	Acne treatment

Use for the treatment of acne

Warnings

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Stop use and ask a doctor if ■ irritation becomes severe

Drug Facts (continued)

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Directions ■ ***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.** ■ clean the skin thoroughly before applying this product ■ cover the entire affected area with a thin layer one to three times daily ■ 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. If irritation or sensitivity develops, stop use of both products and ask a doctor.

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N 3 71399 94789 5

Akron Pharma

Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ- 07004
www.akronpharma.com
Rev.:09/22

Benzoyl Peroxide 5% Gel

Aqueous Base, Acne Treatment Gel

NDC 71399-9478-9

MEDPURA™

Benzoyl Peroxide 5% Gel

Aqueous Base, Acne Treatment Gel

NET.WT 3.2 OZ (90g)

Made in USA

NDC 71399-9478-9

Benzoyl Peroxide 5% Gel

N 3 71399 94789 5

SATISFACTION GUARANTEE

Akron Pharma

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Akron Pharma, Inc.
Fairfield, NJ- 07004
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Rev.:09/22

Benzoyl Peroxide 5% Gel

NDC 71399-9478-9

MEDPURA™

Benzoyl Peroxide 5% Gel

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Benzoyl Peroxide 5% Gel

NDC 71399-9478-9

MEDPURA BENZOYL PEROXIDE AQUEOUS BASE, ACNE TREATMENT GEL

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-9478
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
ALCOHOL (UNII: 3K9958V90M)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE (UNII: 59RU860S8D)	
water (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-9478-5	1 in 1 CARTON	11/04/2021	
1		42.5 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71399-9478-6	1 in 1 CARTON	11/04/2021	
2		60 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:71399-9478-9	1 in 1 CARTON	11/04/2021	
3		90 mL 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			

OTC MONOGRAPH FINAL	part333D	11/04/2021	

MEDPURA BENZOYL PEROXIDE AQUEOUS BASE, ACNE TREATMENT GEL

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-9474
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
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
ALCOHOL (UNII: 3K9958V90M)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE (UNII: 59RU860S8D)	
water (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-9474-5	1 in 1 CARTON	11/04/2021	
1		42.5 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71399-9474-6	1 in 1 CARTON	11/04/2021	
2		60 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:71399-9474-9	1 in 1 CARTON	01/01/2023	

3		90 mL 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 FINAL	part333D	11/04/2021	

Labeler - Akron Pharma Inc. (067878881)

Revised: 3/2023 Akron Pharma Inc.