

ACNE TREATMENT- benzoyl peroxide 10% cream

CVS

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.

☐Do not use

- if you have very sensitive skin or 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.
- rinse right away with water if it gets in eyes.
- avoid unnecessary sun exposure and use a sunscreen.
- avoid contact with 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, possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

☐Stop 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

- cleanse the skin thoroughly before applying medication
- cover the entire affected area with a thin layer one to three times a day
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to 2 to 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, use a sunscreen. Allow product to dry then follow directions in the sunscreen labeling. if sensitivity develops, discontinue use of both products and consult a doctor.

Inactive ingredients

Aluminum hydroxide, Bentonite, Carbomer, Glyceryl Stearate SE, Isopropyl myristate, Methylparaben, PEG-12, Potassium Hydroxide, Propylene Glycol, Propylparaben, Water



CVS Health™ Vanishing Acne Treatment Cream is formulated with 10% benzoyl peroxide to get deep into pores where pimples begin. Its maximum strength formula helps clear existing pimples and prevent new breakouts from forming.

Drug Facts

Active ingredient	Purpose
Benzoyl Peroxide 10%	Acne Treatment

Use for the treatment of acne

Warnings

For external use only

Do not use • if you have very sensitive skin or are sensitive to benzoyl peroxide

When using this product • skin irritation and dryness are 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. • rinse right away with water if it gets in eyes • 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 skin irritation becomes severe

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • cleanse the skin thoroughly before applying medication • cover the entire affected area with a thin layer one to three times a day • 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, use a sunscreen. Allow product to dry, then follow direction in the sunscreen labeling. If sensitivity develops, discontinue use of both products and consult a doctor.

Other information • keep tightly closed • keep away from heat

Inactive ingredients Aluminum Hydroxide, Bentonite, Carbomer, Glyceryl Stearate SE, Isopropyl Myristate, Methylparaben, PEG-12, Potassium Hydroxide, Propylene Glycol, Propylparaben, Water.

ACNE TREATMENT

benzoyl peroxide 10% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59 779 -240
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
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BENTONITE (UNII: A3N5ZCN45C)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-240-01	28 g in 1 TUBE; Type 0: Not a Combination Product	10/31/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/31/2014	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(59779-240) , label(59779-240)

Revised: 12/2017

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