

## **ACNE SPOT 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.*

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### ***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 Acne Spot Treatment***

**☐ *Maximum Strength***

☐ 10% Benzoyl Peroxide



MAXIMUM STRENGTH

# Acne Spot Treatment

10% BENZOYL PEROXIDE

**2.8X MORE**

THAN THE NATIONAL BRAND 0.35 OZ\*



MAXIMUM STRENGTH

# Acne Spot Treatment

10% BENZOYL PEROXIDE

- Contains 3X more Benzoyl Peroxide than the national brand\*
- Helps improve the appearance of existing blemishes & prevent future breakouts
- Dermatologist tested

CVS Health™ Acne Spot Treatment is made with 10% Benzoyl Peroxide, the maximum strength available on the market without a prescription. This spot treatment works fast to clear existing acne and helps prevent new breakouts from forming.



NET WT 1 OZ (28 g)



PLEASE RECYCLE

## 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 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 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. ▶

## Drug Facts (cont.)

### Inactive ingredients

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

\*Panoxyl® Advanced Acne Spot Treatment.

This product is not manufactured or distributed by Stiefel Laboratories, Inc., owner of the registered trademark Panoxyl®.

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## ACNE SPOT TREATMENT

benzoyl peroxide 10% cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-243
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-243-01	1 in 1 CARTON	10/31/2014	
1		28 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 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(59779-243) , label(59779-243)