# MAXIMUM STRENGTH ACNE- benzoyl peroxide 10% gel TopCare

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 Purpose

Benzoyl Peroxide 10%......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 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.

**Inactive ingredients** Carbomer, Disodium EDTA, Disodium Lauryl Sulfosuccinate, Methylparaben, Sodium Hydroxide, Water.

**TopCare**<sub>®</sub>

**MAXIMUM STRENGTH** 

acne gel

invisible formula

dries & clears acne blemishes colorless, odorless, greaseless

**BENZOYL PEROXIDE GEL 10%** 

\*COMPARE TO OXY®

NET WT 1.0 OZ (28 g)

DISTRIBUTED BY TOPCO ASSOCIATES LLC
7711 GROSS POINT ROAD, SKOKIE, IL 60077
© TOPCO PQU1110
QUESTIONS? 1-888-423-0139 topcare@topco.com





\* This product is not manufactured or distributed by

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**TopCare** 



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**Other information** • keep tightly closed • avoid storing at extreme temperatures (below 40°F and above 100°F)

Inactive ingredients Carbomer, Disodium EDTA, Disodium Lauryl Sulfosuccinate, Methylparaben, Sodium Hydroxide, Water.

MAXIMUM STRENGTH acne gel

#### MAXIMUM STRENGTH ACNE

benzoyl peroxide 10% gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-878

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9 WZN9 A0 GM) (BENZO YL PERO XIDE - UNII: W9 WZN9 A0 GM)	Benzoyl Peroxide	10 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Disodium Lauryl Sulfosuccinate (UNII: P160Q81342)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
Methylparaben (UNII: A2I8C7HI9T)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
Sodium Hydroxide (UNII: 55X04QC32I)		

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:36800-878-01	28 g in 1 BOTTLE; Type 0: Not a Combination Product	11/0 1/20 11	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333D	11/0 1/20 11			

## **Labeler -** TopCare (006935977)

### Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-878), label(36800-878)

Revised: 6/2018 TopCare