

# **OXY ADVANCED CARE RAPID SPOT TREATMENT- benzoyl peroxide gel**

## **The Mentholatum Company**

*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
- helps prevent new acne blemishes from forming

#### **Warnings**

##### **For external use only**

##### **Do not use if you**

- have very sensitive skin
- 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.

##### **Stop use and ask a doctor if**

- irritation becomes severe

##### **If pregnant or breast-feeding,**

ask a health professional before use.

## **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer 1 to 3 times daily
- because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 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, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

## **Other Safety Information**

- avoid storing at temperatures above 100 °F (38 °C)

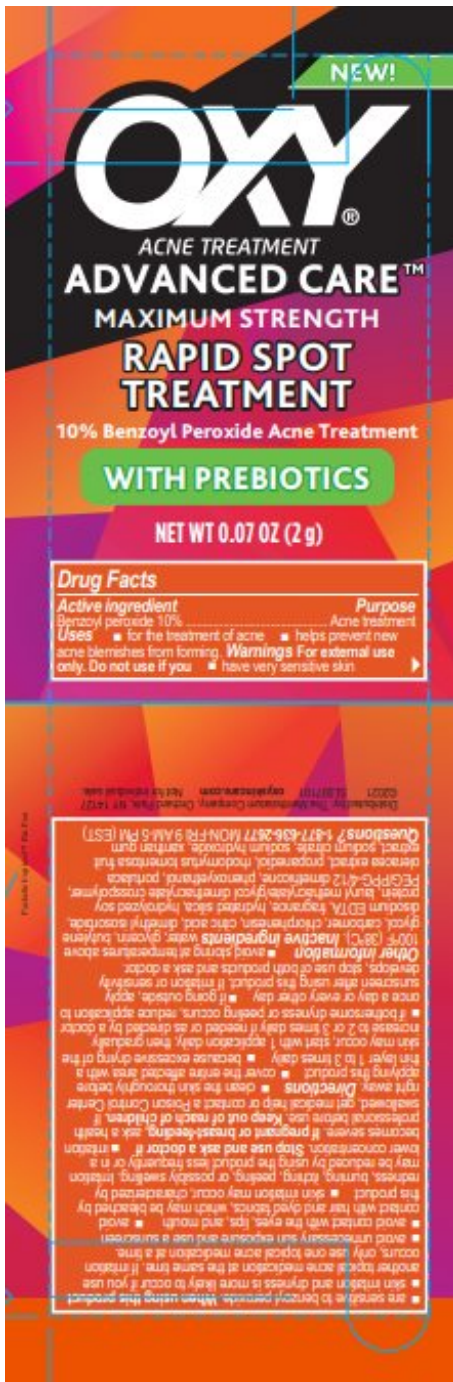
## **Inactive Ingredients**

water, glycerin, butylene glycol, carbomer, chlorphenesin, citric acid, dimethyl isosorbide, disodium EDTA, fragrance, hydrated silica, hydrolyzed soy protein, lauryl methacrylate/glycol dimethacrylate crosspolymer, PEG/PPG-4/12 dimethicone, phenoxyethanol, portulaca oleracea extract, propanediol, rhodomyrtus tomentosa fruit extract, sodium citrate, sodium hydroxide, xanthan gum

## **Questions**

1-877-636-2677 MON-FRI 9 AM-5 PM (EST)

## **Package/Label Principal Display Panel**



## OXY ADVANCED CARE RAPID SPOT TREATMENT

benzoyl peroxide gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-1205
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 mg in 1 g
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## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>SOY PROTEIN</b> (UNII: R44IWB3RN5)	
<b>LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EX0F4CZ66H)	
<b>PEG/PPG-4/12 DIMETHICONE</b> (UNII: JAN3585W85)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PURSLANE</b> (UNII: M6S840WYG5)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>RHODOMYRTUS TOMENTOSA FRUIT</b> (UNII: Q99511S58K)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-1205-1	2 g in 1 POUCH; Type 0: Not a Combination Product	03/31/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	03/31/2022	

**Labeler** - The Mentholatum Company (002105757)