

## **OXY TOTAL CARE CLARIFYING MOISTURIZER- benzoyl peroxide lotion**

### **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 2.5%

#### **Purpose**

Benzoyl peroxide - Acne treatment

#### **Keep Out of Reach of Children**

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

#### **Uses**

- For the treatment of acne.
- Helps prevent new acne blemishes.

#### **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, use only 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.

## **Directions**

- clean the skin thoroughly before applying this product
- use a dime-sized amount to cover the entire affected area with a thin layer one to two 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.
- *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 above.

## **Other information**

- THIS PRODUCT MAY BLEACH HAIR OR DYED FABRICS
- KEEP TIGHTLY CLOSED
- avoid storing at temperatures above 100°F (38°C)

## **Inactive Ingredients**

water, glycerin, butylene glycol, carbomer, chlorphenesin, citric acid, dimethyl isosorbide, disodium EDTA, hyaluronic acid, hydrolyzed algin, lauryl methacrylate/glycol dimethacrylate crosspolymer, PEG/PPG-4/12 dimethicone, phenoxyethanol, phytic acid, portulaca oleracea extract, silanetriol, sodium citrate, sodium hydroxide, xanthan gum, zinc sulfate

## **Questions?1-877-636-2677**

MON-FRI 9AM-5PM (EST)

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



# OXY TOTAL CARE CLARIFYING MOISTURIZER

benzoyl peroxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-1314
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	25 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)	
<b>ALGINIC ACID</b> (UNII: 8C3Z4148WZ)	
<b>LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EX0F4CZ66H)	
<b>PEG/PPG-4/12 DIMETHICONE</b> (UNII: JAN3585W85)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>FYTIC ACID</b> (UNII: 7IGF0S7R8I)	
<b>PURSLANE</b> (UNII: M6S840WYG5)	
<b>SILANETRIOL</b> (UNII: E52D0J3TS5)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ZINC SULFATE HEPTAHYDRATE</b> (UNII: N57J12K7WP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-1314-1	1 in 1 CARTON	09/30/2019	
1		100 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	09/30/2019	

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

## Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-1314)

Revised: 2/2023

The Mentholatum Company