

**OXY 5 TINTED- 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 5%

**Purpose**

Acne treatment

**Uses**

treats and helps prevent acne

**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 this 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 skin thoroughly before applying this product
- cover 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.

## **Inactive Ingredients**

carbomer homopolymer, diazolidinyl urea, diethylhexyl sodium sulfosuccinate, edetate disodium, iron oxide, purified water, sodium hydroxide, talc, titanium dioxide

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



**OXY 5 TINTED**  
benzoyl peroxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-8356
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	50 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10742-8356-1	1 in 1 CARTON	07/01/2015	
1		30 g in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part333D	07/01/2015	

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

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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Revised: 2/2023

The Mentholatum Company