OXY 10 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.

Drug Facts

Active ingredient

Benzoyl peroxide 10%

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, diethylhexyl sodium sulfosuccinate, edetate disodium, iron oxide, purified water, sodium hydroxide, talc, titanium dioxide

Package/Label Principal Display Panel

OXY 10 TINTED

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8354
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 mg in 1 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8354-1	1 in 1 CARTON	07/01/2015	
1		30 g in 1 BOTTLE; 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	07/01/2015	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8354)