

OXY 10 TINTED- benzoyl peroxide lotion
The Mentholatum Company

Drug Facts - Oxy 10 Tinted

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.

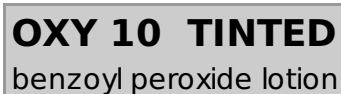
Directions

- 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



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 Drug	M006	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)

