OXY MAXIMUM ACTION SPOT TREATMENT TINTED- benzoyl peroxide cream 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.

Other information

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

Inactive ingredients

anhydrous citric acid, butylene glycol, carbomer homopolymer, diazolidinyl urea, dimethicone, dimethyl isosorbide, edetate disodium, fragrance, glycerin, iodopropynyl butylcarbamate, iron oxides, lauryl methacrylate/glycol dimethacrylate crosspolymer, PEG-8 methyl ether triethoxysilane, PEG/PPG-4/12 dimethicone, portulaca oleracea extract, propylene glycol, purified water, silica, sodium citrate, sodium hydroxide, talc, titanium dioxide, xanthan gum

Questions?

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

Package/Label Principal Display Panel



OXY MAXIMUM ACTION SPOT TREATMENT TINTED

benzoyl peroxide cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:10742-8302
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZO YL PERO XIDE (BENZO YL PERO XIDE)	BENZOYL PEROXIDE	100 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US CITRIC ACID	

CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) DIAZO LIDINYL UREA DIMETHICONE DIMETHYL ISOSORBIDE EDETATE DISODIUM GLYCERIN IODO PRO PYNYL BUTYLCARBAMATE FERRIC O XIDE RED FERRIC O XIDE YELLO W LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER PEG/PPG-4/12 DIMETHICONE PURSLANE PRO PYLENE GLYCOL WATER SILICON DIO XIDE SODIUM CITRATE SODIUM CITRATE SODIUM HYDRO XIDE	BUTYLENE GLYCOL	
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PURSLANE PROPYLENE GLYCOL WATER SILICON DIO XIDE SODIUM CITRATE SODIUM HYDRO XIDE	LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER	
PROPYLENE GLYCOL WATER SILICON DIO XIDE SODIUM CITRATE SODIUM HYDRO XIDE	PEG/PPG-4/12 DIMETHICO NE	
WATER SILICON DIO XIDE SODIUM CITRATE SODIUM HYDRO XIDE	PURSLANE	
SILICON DIO XIDE SO DIUM CITRATE SO DIUM HYDRO XIDE	PROPYLENE GLYCOL	
SODIUM CITRATE SODIUM HYDROXIDE	WATER	
SO DIUM HYDRO XIDE	SILICON DIO XIDE	
	SODIUM CITRATE	
TALC	SO DIUM HYDRO XIDE	
IALC	TALC	
TITANIUM DIO XIDE	TITANIUM DIO XIDE	
XANTHAN GUM	XANTHAN GUM	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8302-1	1 in 1 CARTON		
1		18.4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	0 1/15/20 13	

Labeler - The Mentholatum Company (002105757)

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