OXY ADVANCED CARE SOOTHING CREAM ACNE CLEANSER- benzoyl peroxide gel
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

- for the treatment of acne
- clears acne pimples and allows skin to heal
- penetrates pores to control blackheads and whiteheads
- helps prevent new acne pimples from forming

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 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.

Keep out of reach of children.

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

Directions

- wet face
- apply to hands then work into a lather and massage gently onto face
- rinse thoroughly and pat dry
- 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

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

Inactive ingredients

water, cetostearyl alcohol, sodium C14-16 olefin sulfonate, disodium laureth sulfosuccinate, capryl/capramidopropyl betaine, xanthan gum, butylene glycol, chlorphenesin, citric acid, fragrance, glycerin, hydrolyzed soy protein, hydroxyphenyl propamidobenzoic acid, PEG-8 dimethicone, pentylene glycol, phenoxyethanol, propanediol, rhodomyrtus tomentosa fruit extract, sodium citrate, sodium hydroxide, sodium lauroyl sarcosinate

Questions?

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

Package/Label Principal Display Panel

OXY ADVANCED CARE SOOTHING CREAM ACNE CLEANSER

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-1202
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 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	
CAPRYL/CAPRAMIDOPROPYL BETAINE (UNII: 231H3ZT9NE)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOY PROTEIN (UNII: R44IWB3RN5)	
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
RHODOMYRTUS TOMENTOSA FRUIT (UNII: Q99511S58K)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-1202-1	148 mL in 1 TUBE; Type 0: Not a Combination Product	09/01/2021	
2	NDC:10742-1202-2	185 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/01/2021	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-1202)