CLENZIDERM THERAPEUTIC- benzoyl peroxide lotion Obagi Cosmeceuticals LLC

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.

CLENZIDERM THERAPEUTIC LOTION

Drug Facts

Active ingredient

Benzoyl Peroxide 5%

Purpose

Acne treatment

Use

for the treatment of acne

Warnings

For external use only

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 the product less frequently or in a lower concentration.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide.

Stop use and ask a doctor if irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Cleanse the skin thoroughly before applying this product
- Cover the entire affected area with a thin layer one to three times daily
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three 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

- Store away from heat and direct sunlight.
- Store at controlled room temperature: 15°-25°C (59°-77°F).

Inactive ingredients

benzyl benzoate, BHT, dicaprylyl ether, dimethyl isosorbide, disodium EDTA, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, phenoxyethanol, polysorbate 60, propylene glycol, squalane, water (aqua)

Questions or comments?

1.800.636.7546

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - 47 mL Bottle Label

OBAGI[®] MEDICAL

CLENZIderm M.D.™

Therapeutic Lotion

Benzoyl Peroxide 5% Acne Treatment

SoluZyl Technology[®] delivers medication within the pores where acne starts, helping to clear acne quickly, in as early as one week.

1.6fl. oz. (47mL)



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Made in USA with U.S. and Imported components 9426502

CLENZIDERM THERAPEUTIC

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-611
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII: W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
BENZYL BENZOATE (UNII: N863NB338G)				
DICAPRYLYL ETHER (UNII: 77JZM5516Z)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)				
SQUALANE (UNII: GW89575KF9)				
POLYSORBATE 60 (UNII: CAL22UVI4M)				
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
WATER (UNII: 059QF0KO0R)				

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:62032- 611-01	47 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2007	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333D	07/01/2007		

Establishment				
Name	Address	ID/FEI	Business Operations	
G.S.COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-611)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Denison Pharmaceuticals, LLC		001207208	MANUFACTURE(62032-611)	

Revised: 3/2021 Obagi Cosmeceuticals LLC