BENZOYL PEROXIDE- benzoyl peroxide gel
GERITREX 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.

Benzoyl Peroxide Gel

Drug Facts

Active Ingredient Purpose

Benzoyl Peroxide 10% Acne Treatment

Use

For the treatment of acne

Directions

Shake well, wet face, apply to hands, add water, work into a lather, and massage gently onto face. Rinse thoroughly and pat dry

use 2 to 3 times daily or as directed by a doctor if bothersome dryness of peeling occurs, reduce application to once a day or every other

day if going outside use sunscreen. After washing and drying face follow directions in the sunscreen labeling if irritation or sensitivity develops,

discontinue use of both products and consult a doctor

Warnings

For external use only

Do not use if you have very sensitive skin of if you are sensitive to benzoyl peroxide

When using this product avoid unnecessary sun exposure and use a sunscreen using other topical acne drugs at the same time or right

after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a

doctor. Irritation may develop, such as redness, burning, itching, peeling, or possibly swelling more frequent use or higher concentraions may

aggravate such irritation: mild irritation may be reduced by using the product less frequently or in lower concnetraion. Keep away from eyes,

lips, mouth It may bleach hair of dye fabrics

Stop use and ask a doctor if irritaion becomes severe and continue.

Inactive Ingrdients

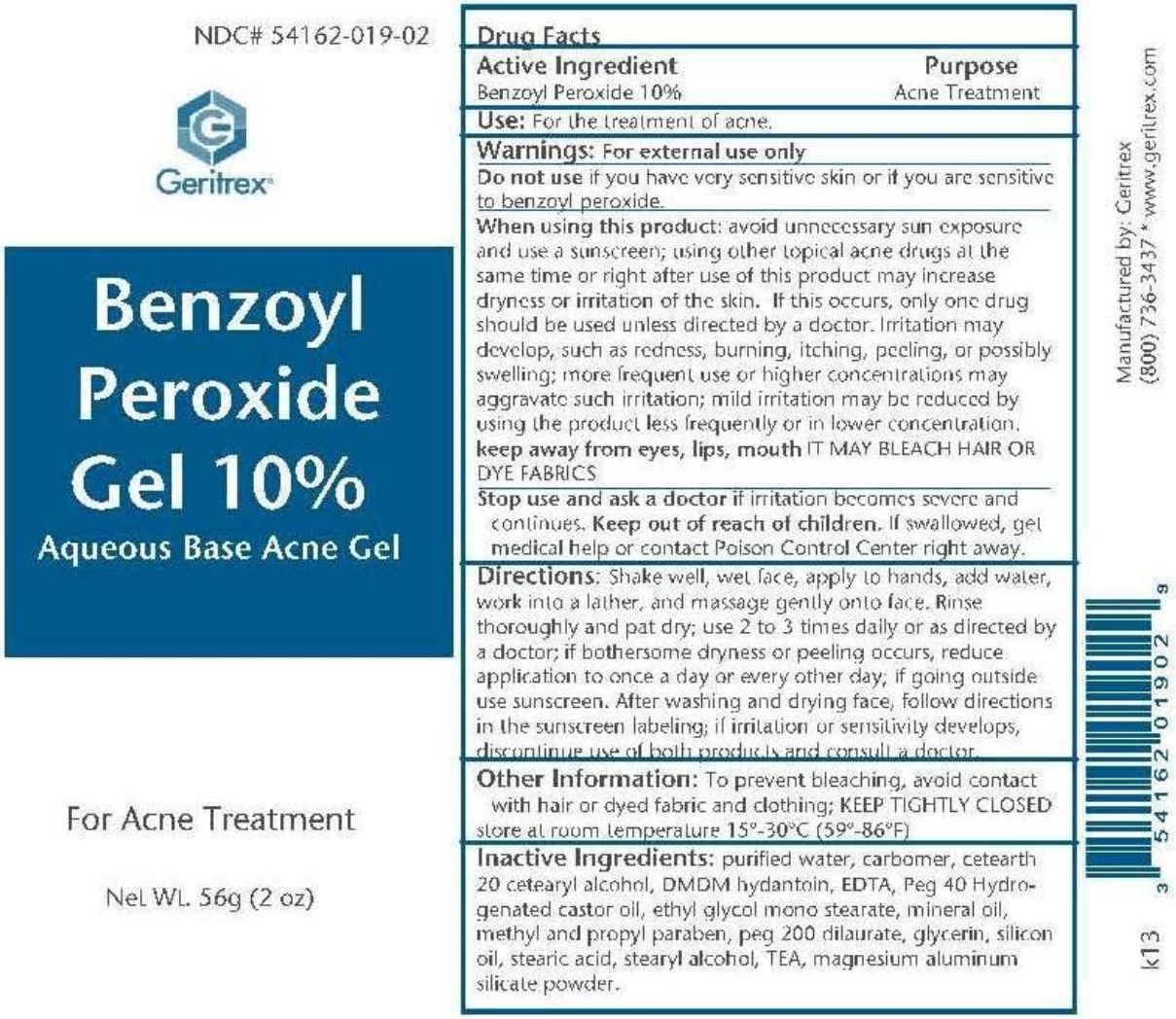
Purified water, Carbomer, Cetearth 20 cetearyl alcohol, DMDM Hydantoin, EDTA, Peg 40 Hydrogenated castor oil, Ethyl Glycol Mono Stearate, Mineral Oil, Methyl and Propyl Paraben, Peg 200 dilurate, Glycerin, silicon oil, Stearic acid, stearyl alcohol, TEA, Magnesium aluminium silicate

powder

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

Store at room temperature 15°-30°C (59°-86°F)

Use 2 to 3 times daily or as directed by a doctor.



BENZOYL PEROXIDE

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	10 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PEG-200 DILAURATE (UNII: TWV5J70L88)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON (UNII: Z4152N8IUI)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
DIETHYLENE GLYCOL DISTEARATE (UNII: 617Q4OD69O)	
DISODIUM HEDTA (UNII: KME849MC7A)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54162-019-02	56 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/31/2015	

Labeler - GERITREX LLC (112796248)

Registrant - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-019)

Revised: 8/2016 GERITREX LLC