24 HOUR ACNE SERUM - benzoyl peroxide gel
Neutraderm, Inc.

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.

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24 Hour Acne Serum

Drug Facts

Active ingredient

Benzoyl Peroxide 5%

Purpose

Acne Medication

Use

For the treatment of acne.

Warnings

For external use only.

When using this product • avoid unnecessary sun exposure and use sunscreen. • avoid contact with eyes, lips and mouth. • avoid contact with hair and dyed products, 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

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

Directions

• Clean the skin thoroughly before applying this product. Apply affected area with a thin layer, avoiding eye area. Allow to absorb before applying additional products. Can be used twice daily or as directed by physician. If irritation or sensitivity develops, stop use of product and consult physician.

Inactive Ingredients

Water, Glycolic Acid, Sclerotium Gum, Arnica Montana Flower Extract, Allantoin, Echinacea Purpurea Extract, Hydrastis Canadensis (Goldenseal) Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Calendula Officinalis Flower Extract, Glycerin, Gluconolactone, Sodium Benzoate, Tetrasodium EDTA, Sodium Hydroxide

D R M T L G Y®

MEDICAL GRADE SKIN CARE

Quickly Dries Breakouts

Prevents New Breakouts

Effective for Body and Face

DRMTLGY, LLC • Chatsworth, CA

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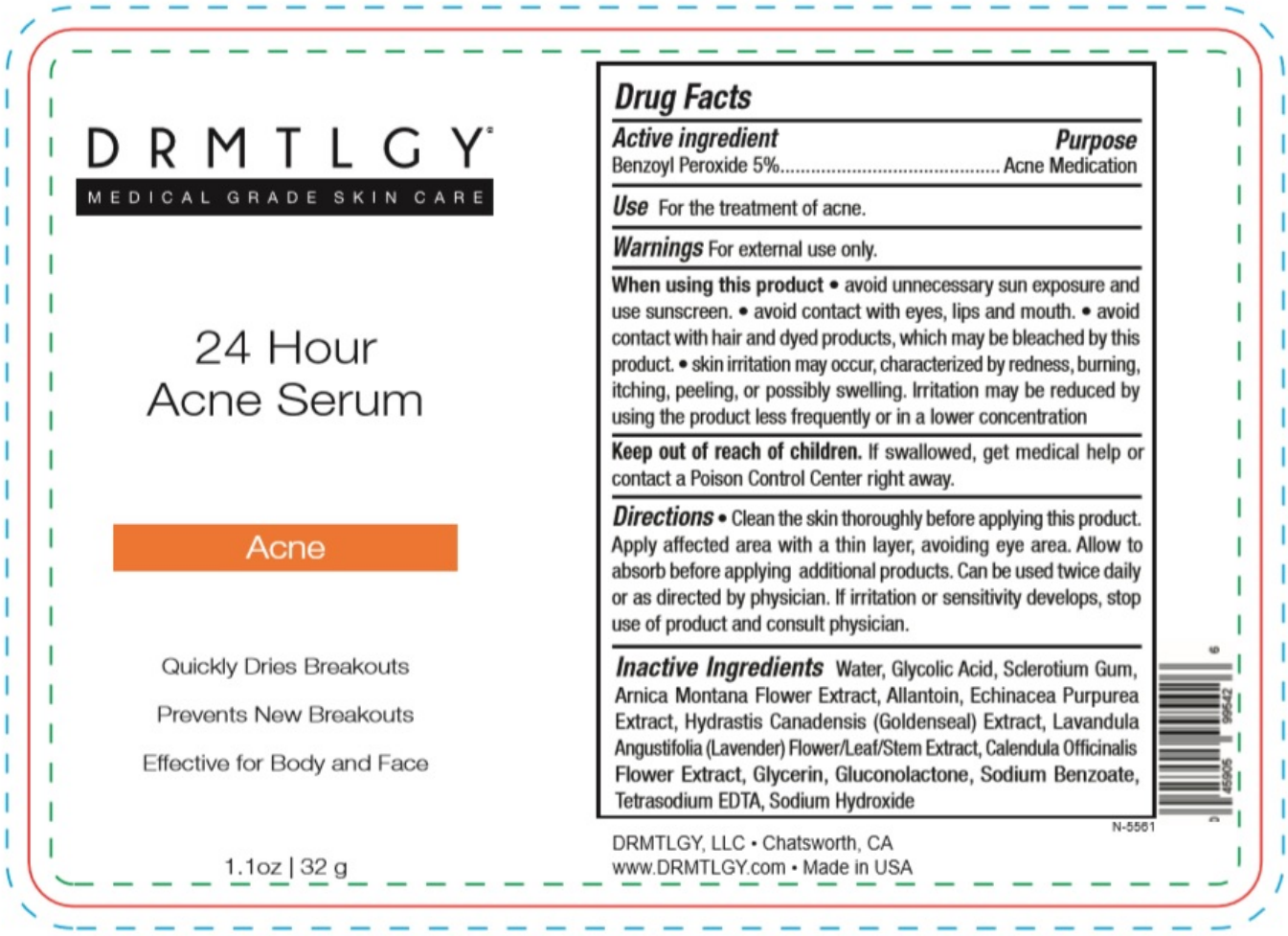
Packaging



24 HOUR ACNE SERUM

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:39765-034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALLANTOIN (UNII: 344S277G0Z)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color	white (White to Off White)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:39765-034-01	32 g in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/08/2019	

Labeler - Neutraderm, Inc. (146224444)

Establishment

Name	Address	ID/FEI	Business Operations
Neutraderm, Inc.		146224444	manufacture(39765-034)

Revised: 6/2019 Neutraderm, Inc.