

BENZOYL PEROXIDE 10% GEL- benzoyl peroxide gel
Axia Medical Solutions, 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.

Dermesse Benzoyl Peroxide 10% Gel

Active Ingredient:

Benzoyl Peroxide 10%

Purpose

Acne Treatment

USES:

For the treatment of acne.

WARNINGS:

For external use only.

Do not use if you:

- Have sensitive skin.
- Are sensitive to benzoyl peroxide.

When using the product:

• Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If this 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.

Stop use and ask a doctor if:

Irritation become severe.

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 • 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 to 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.

Inactive Ingredients:

Allantoin, Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Disodium Laureth Sulfosuccinate, Glycerin, Panthenol, PEG-8, PEG-14 Palmeth-60 Hexyl Dicarbamate, Sodium Hyaluronate, Triethanolamine, and Water.

OTHER INFORMATION:

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

Questions?:

866-494-4466, Mon-Fri 8:00AM-5:00PM

Dist. By Axia Medical Solutions, 2105 Camino Vida Roble, Carlsbad, Ca. 92011

www.dermesse.com 866-494-4466 office, 760-931-8267 fax

DERMESSE™

For the treatment of acne. Dries up acne pimples. Helps prevent new acne pimples from forming while minimizing dryness.

BENZOYL PEROXIDE 10% GEL

2 fl.oz. (57mL)

DRUG FACTS

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BENZOYL PEROXIDE 10% GEL			
benzoyl peroxide gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 723-306
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 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PPG-14 PALMETH-60 HEXYL DICARBAMATE (UNII: 376C96Y6AL)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68723-306-02	59.3 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/01/2014	

Labeler - Axia Medical Solutions, LLC (929224694)**Establishment**

Name	Address	ID/FEI	Business Operations
Axia Medical Solutions, LLC		929224694	manufacture(68723-306)