

ADVANCED ACNE WASH- benzoyl peroxide liquid, extended release
Elorac, 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.

Advanced Acne Wash (4.4% benzoyl peroxide extended release)

Continuous Action for Lasting Results

4.4% Benzoyl Peroxide

Dermatologist Developed

▣ Drug Facts

▣ Active Ingredient

Benzoyl peroxide 4.4%

▣ Purpose

Acne treatment

▣ Uses

For the treatment of acne

▣ Warnings

For external use only

▣ Do not use if you

have very sensitive skin

are sensitive to benzoyl peroxide

▣ When using this product

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.

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.

▣ 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 immediately.

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 one application daily, then increase to 2 times daily if needed or as directed by a doctor

If bothersome dryness or peeling occurs, reduce usage 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

Butyrospermum Parkii (Shea) Butter, C13-14 Isoparaffin, Cocamidopropyl Betaine, Ethylhexylglycerin, Euphorbia Cerifera (Candelilla) Wax, Hydroxyethyl Behenamidopropyl Dimonium Chloride, Laureth-7, Phenoxyethanol, Polyacrylamide, Water

Questions?

1-847-362-8200 MON - FRI 9 AM - 5 PM (CST)

Advanced Acne Wash

Extended - release action for lasting results

Kills bacteria that cause acne

Gentle formula

Manufactured for Elorac, Inc.

Vernon Hills, IL 60061

U.S. Patent No. 6979440

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NDC 42783-635-04

Elorac, Inc.

Advanced Acne Wash



Advanced Acne Wash

(4.4% Benzoyl Peroxide
Extended Release)

Continuous Action
for Lasting Results

Dermatologist
Developed
3.5 FL OZ (104 mL)



Manufactured for Elorac, Inc.
Vernon Hills, IL 60061

U.S. Patent No. 6979440



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Drug Facts		Advanced Acne Wash
Active Ingredient Benzoyl peroxide 4.4%	Purpose Acne treatment	<ul style="list-style-type: none"> Extended-release action for lasting results Kills bacteria that causes acne Gentle formula
Uses For the treatment of acne		
Warnings: For external use only		
Do not use if you ■ have very sensitive skin ■ are sensitive to benzoyl peroxide		
When using this product ■ 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 low concentration. ■ 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.		
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 immediately.		
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 one application daily, then increase to 2 times daily if needed or as directed by a doctor. ■ If bothersome dryness or peeling occurs, reduce usage 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 butyrospermum parkii (shea) butter, C13-14 isoparaffin, cocamidopropyl betaine, ethylhexylglycerin, euphorbia cerifera (candelilla) wax, hydroxyethyl behenamidopropyl dimonium chloride, laureth-7, phenoxyethanol, polyacrylamide, water		
Questions? 1-847-362-8200 MON - FRI 9 AM - 5 PM (CST)		

ADVANCED ACNE WASH

benzoyl peroxide liquid, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42783-635
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	44 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CANDELILLA WAX (UNII: WL0328HX19)	
HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE (UNII: 9CO8OUL4TH)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42783-635-04	104 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/17/2015	

Labeler - Elorac, Inc. (832590009)

Registrant - Elorac, Inc. (832590009)

Revised: 10/2015

Elorac, Inc.