

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE EFFACLAR DUO ACNE
TREATMENT- benzoyl peroxide lotion
L'OREAL USA, 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.

Drug Facts

Active ingredient

Benzoyl peroxide 5.5%

Purpose

Acne medication

Uses

- for the treatment of acne
- dries and clears acne blemishes and allows skin to heal

Warnings

For external use only

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

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.

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

- 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 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 at 20 - 25 C (68 to 77 F)

Inactive ingredients

water, isostearyl alcohol, glycerin, pentylene glycol, silica, carbomer, capryloyl salicylic acid, potassium hydroxide, tocopheryl acetate, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, epilobium angustifolium flower/leaf/stem extract

Questions or comments?

1-888-LRP-LABO 1-888-577-5226

Monday - Friday (9 a.m. - 5 p.m. EST)

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69322627 Code F.I.L.: D164973/4

The EFFACLAR skincare range is designed to provide dermatologists with an efficient solution to address oily and acne-prone skin. Effaclar featuring LHA, a unique micro-exfoliating agent, is formulated to reveal smoother, healthier-looking skin.

For more information on EFFACLAR DUO or the rest of the EFFACLAR line of products please visit us at: www.laroche-posay.us



LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

ACNE BLEMISHES.
BLACKHEADS.
WHITEHEADS

EFFACLAR
DUO
DUAL ACTION
ACNE TREATMENT

5.5% BENZOYL PEROXIDE
ACNE MEDICATION

MICRO-EXFOLIATING LHA

Reduces the number and severity of acne blemishes
Clears blackheads & whiteheads

TESTED ON ACNE-PRONE SKIN
OIL-FREE. NON-COMEDOGENIC

40 ml - 1.35 FL.OZ.

FOR

Acne-prone skin with acne blemishes, blackheads and whiteheads.

It is the first treatment to combine:

- 5.5% micronized benzoyl peroxide acne medication to penetrate pores to clear up acne blemishes.

- LHA (Lipo-Hydroxy-Acid) a bead-free micro-exfoliating ingredient

- Moisturizing and soothing skincare agents.

DUAL ACTION INNOVATION.

EFFACLAR DUO reduces both:

1/ Acne blemishes

The formula reduces the number and severity of acne blemishes.

2/ Blackheads & whiteheads

The formula penetrates clogged pores to clear blackheads and whiteheads.

RESULTS.

Whiteheads, blackheads and acne blemishes are effectively treated. Skin looks clearer and smoother.

Non-drying, oil-free formula is easily absorbed.

Visible results in 3 days.

SENSITIVE SKIN TESTED

OIL-FREE

NON-COMEDOGENIC

FRAGRANCE-FREE

PARABEN-FREE

DERMATOLOGIST TESTED

FOR SAFETY

TESTED ON

ACNE-PRONE SKIN

2705655

Made in USA of USA and/or Imported
Ingredients

Distribution reserved to La Roche-Posay
agreed distributors.
La Roche-Posay LLC,
10 Hudson Yards,
New York, NY 10001

La Roche-Posay
Laboratoire Dermatologique
CAI 86270 La Roche-Posay, France
TSA 75000 F 93584 ST. OUEEN CEDEX FR
www.laroche-posay.us

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE EFFACLAR DUO
ACNE TREATMENT**

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl peroxide (UNII: W9WZN9A0GM) (Benzoyl peroxide - UNII:W9WZN9A0GM)	Benzoyl peroxide	55 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-076-01	1 in 1 CARTON	07/01/2012	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-076-02	1 in 1 CARTON	07/01/2012	
2		20 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:49967-076-03	3 mL in 1 PACKET; Type 0: Not a Combination Product	07/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/01/2012	

Labeler - L'OREAL USA, INC. (002136794)**Establishment**

Name	Address	ID/FEI	Business Operations
Beauty Manufacturing Solutions Corp.		783200723	manufacture(49967-076) , pack(49967-076)

Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		185931458	analysis(49967-076)