

**LA ROCHE-POSAY EFFACLAR DUO DUAL ACTION ACNE TREATMENT- benzoyl peroxide lotion**  
**Beauty Manufacturing Solutions Corp**

*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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**La Roche-Posay Effaclar Duo**

Benzoyl Peroxide 5.5%

Purpose Acne Medication

Acne medication

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

For external use only

- have very sensitive skin
- are sensitive to benzoyl peroxide
- 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

irritation becomes severe

If swallowed, get medical help or contact a Poison Control Center right away.

- 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.

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

water, isostearyl alcohol, glycerin, pentylene glycol, silica, carbomer, capryloyl salicylic acid, potassium hydroxide, tocopheryl acetate, acrylates/C10-30 alkyl acrylate



## Drug Facts

**Active ingredient**      **Purpose**  
Benzoyl peroxide 5.5%..... 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
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- 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
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### 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?

Monday - Friday (9 a.m. - 5 p.m. EST)  
1-888-LRP-LABO 1-888-577-5226

693226 27 Code F.J.L.: D164973/4

Can be used alone or as  
**STEP 3** of the **EFFACLAR**  
Dermatological Acne System



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  
0.7 FL.OZ. - 20 ml

### 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. Visible results in 3 days.

OIL-FREE  
NON COMEDOGENIC  
FRAGRANCE-FREE  
PARABEN-FREE  
SENSITIVE SKIN TESTED  
DERMATOLOGIST TESTED  
FOR SAFETY

2232849  
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 P 93584 ST QUEN CEDEX FR  
[www.laroche-posay.us](http://www.laroche-posay.us)

## Drug Facts

**Active ingredient Purpose**  
Benzoyl peroxide 5.5%... 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.

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### 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-LA BO 1-888-577-5226  
Monday - Friday (9 a.m. - 5 p.m. EST)

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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](http://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

Z105655

Made in 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  
CA 1 86270 La Roche-Posay, France  
TSA 75000 F 93584 ST OUEX CEDEX FR  
[www.laroche-posay.us](http://www.laroche-posay.us)



**LA ROCHE-POSAY EFFACLAR DUO DUAL ACTION ACNE TREATMENT**

benzoyl peroxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11090-223
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	55 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOSTEARYL ALCOHOL</b> (UNII: Q613OCQ44Y)	
<b>EPILOBIUM ANGUSTIFOLIUM WHOLE</b> (UNII: C278QS9YBT)	
<b>CAPRYLOYL SALICYLIC ACID</b> (UNII: 5F7PJF6AA4)	
<b>CARBOMER COPOLYMER TYPE A</b> (UNII: 71DD5V995L)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11090-223-01	20 in 1 CARTON	07/01/2012	
1		3 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11090-223-02	1 in 1 CARTON	07/01/2012	
2		20 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11090-223-03	1 in 1 CARTON	07/01/2012	
3		40 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	07/01/2012	
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**Labeler** - Beauty Manufacturing Solutions Corp (783200723)

**Registrant** - Beauty Manufacturing Solutions Corp (783200723)

**Establishment**

Name	Address	ID/FEI	Business Operations
Beauty Manufacturing Solutions Corp		783200723	manufacture(11090-223)

Revised: 2/2022

Beauty Manufacturing Solutions Corp