#### LA ROCHE POSAY EFFACLAR DERMATOLOGICAL ACNE SYSTEM 3 STEP ACNE ROUTINE- benzoyl peroxide and salicylic acid L'Oreal USA Products Inc

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#### **Drug Facts**

#### Effaclar Medicated Gel Cleanser

**Drug Facts** 

#### **Active ingredient**

Salicylic acid 2%

#### Purpose

Acne treatment

#### Use

for the treatment of acne

#### Warnings

For external use only

#### When using this product

 skin irritation and dryness is more liekly 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.

#### Keep out of reach of children.

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

#### Directions

- use twice daily
- wet face, then work product into a lather
- massage onto face avoiding the eyes
- rinse well

#### **Inactive Ingredients**

water, sodium laureth sulfate, decyl glucoside, glycerin, sodium chloride, coco-betaine,

sodium hydroxide, PEG-150 pentaerythrityl tetrastearate, citric acid, hexylene glycol, PEG-6 caprylic/capric glycerides, zinc gluconate, tetrasodium EDTA, polyquaternium-47, menthol, capryloyl salicylic acid, sodium benzoate

# **Questions or comments?**

# 1-888-577-5226

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

# **Effaclar Clarifying Solution**

**Drug Facts** 

# **Active ingredient**

Salicylic acid 0.5%

# Purpose

Acne treatment

### Use

for the treatment of acne

# Warnings

For external use only

# 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.

# 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 information

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing and limit sun exposure while using this product and for a week afterwards.

#### **Inactive Ingredients**

water, alcohol denat., propanediol, glycolic acid, sodium hydroxide, capryloyl glycine, phenoxyethanol, benzyl alcohol, PPG-26-buteth-26, PEG-40 hydrogenated castor oil, menthol, tremella fuciformis polysaccharide, butylene glycol, ophiopogon japonicus root extract, scutellaria baicalensis root extract

#### Questions or comments?

1-888-577-5626

### **Effaclar Duo Dual Action Acne Treatment**

### **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

- cleanse 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° - 77°F)

### 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)



C1 - Internal use







C1 - Internal use

### LA ROCHE POSAY EFFACLAR DERMATOLOGICAL ACNE SYSTEM 3

Product Informa	tion					
Product Type	HUMAN C	TC DRUG	ltem Code (Sourc	e)	NDC:499	67-282
				-,		
Packaging						
# Item Code	Packad	e Description	Marketing Star	t Date	Marketing	g End Date
<b>1</b> NDC:49967-282-01	1 in 1 CART	-	01/01/2015		Marketing	
I NDC.49907-202-01	IMICAN		01/01/2015			
Quantity of Parts	5					
Part # Pa	ackage Q	uantity	Tot	al Produc	t Quantity	,
Part 1 1 TUBE			100 mL			
Part 2 1 BOTTLE			100 mL			
Part 3 1 TUBE			20 mL			
Part 1 of 3						
LA ROCHE PO	SAY EF	FACLAR ME	EDICATED GE	L CLEA	NSER	
salicylic acid gel						
Product Informa	tion					
Route of Administra	ation	ΤΟΡΙζΑΙ				
Route of Administra	ation	TOPICAL				
	Active I	Moiety		Basis of	Strength	Strength
Active Ingredient	Active I	Moiety ient Name			Strength	Strength
Active Ingredient	Active I	Moiety ient Name	- UNII:O414PZ4LPZ)	<b>Basis of</b> SALICYLIC A	_	-
Active Ingredient	Active I	Moiety ient Name	- UNII:O414PZ4LPZ)		_	<b>Strength</b> 20 mg in 1 ml
Active Ingredient SALICYLIC ACID (UNII: (	Active I Ingred	Moiety ient Name Z) (SALICYLIC ACID			_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie	Active I Ingred 0414PZ4LP2 nts	Moiety ient Name			_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC	Active I Ingred 0414PZ4LP2 nts	Moiety ient Name Z) (SALICYLIC ACID Ingredient			_	-
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC SODIUM LAURETH SUL	CACTIVE I Ingred 0414PZ4LP2 nts DOR) FATE (UNII:	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0)			_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC SODIUM LAURETH SUL DECYL GLUCOSIDE (UN	Active I Ingred 0414PZ4LP2 nts DOR) FATE (UNIII: NIII: Z17H97E	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0)			_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC SODIUM LAURETH SUL DECYL GLUCOSIDE (UN GLYCERIN (UNII: PDC6A	:/Active I Ingred 0414PZ4LP2 nts DOR) .FATE (UNII: XIII: Z17H97E 3C00X)	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0) EAGY)			_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: 0 Inactive Ingredie WATER (UNII: 059QF0K0 SODIUM LAURETH SUL DECYL GLUCOSIDE (UN GLYCERIN (UNII: PDC6A SODIUM CHLORIDE (UN	:/Active I Ingred 0414PZ4LP2 nts DOR) .FATE (UNII: XIII: Z17H97E 3C0OX) NIII: 451W47I	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0) EAGY) Q8X)			_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC SODIUM LAURETH SUL DECYL GLUCOSIDE (UN GLYCERIN (UNII: PDC6A SODIUM CHLORIDE (UNII: (	2/Active I Ingred 0414PZ 4LP2 nts 00R) .FATE (UNII: 3C00X) NII: Z 17H97E 3C00X) NII: 451W47I 03DH2IZ 3FY	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0) EA6Y) Q8X) )			_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC SODIUM LAURETH SUL DECYL GLUCOSIDE (UN GLYCERIN (UNII: PDC6A SODIUM CHLORIDE (UNII: ( SODIUM HYDROXIDE (U	:/Active I ingred 0414PZ4LP2 nts 00R) .FATE (UNII: 217H97E 3C00X) NII: 451W47I 03DH2IZ3FY UNII: 55X040	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0) EAGY) Q8X) ) Q2C32I)	t Name		_	20 mg in 1 m
Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC SODIUM LAURETH SUL DECYL GLUCOSIDE (UN GLYCERIN (UNII: PDC6A SODIUM CHLORIDE (UN COCO-BETAINE (UNII: ( SODIUM HYDROXIDE (( PEG-150 PENTAERYTH	:/Active I ingred 0414PZ 4LP2 0414PZ 4LP2 nts 00R) .FATE (UNII: SII: Z 17H97E 3C00X) NII: Z 17H97E 3C00X) NII: 451W47I 03DH2IZ 3FY UNII: 55X040 IRITYL TET	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0) EA6Y) Q8X) ) Q8X) ) Q2C32I) RASTEARATE (UNII	t Name		_	20 mg in 1 m
Route of Administra Active Ingredient SALICYLIC ACID (UNII: ( Inactive Ingredie WATER (UNII: 059QF0KC SODIUM LAURETH SUL DECYL GLUCOSIDE (UN GLYCERIN (UNII: PDC6A SODIUM CHLORIDE (UN COCO-BETAINE (UNII: ( SODIUM HYDROXIDE (U PEG-150 PENTAERYTH CITRIC ACID MONOHY HEXYLENE GLYCOL (U	:/Active I ingred 0414PZ4LP2 nts 00R) .FATE (UNII: XII: Z17H97E 3C00X) XII: 451W47I 03DH2IZ3FY UNII: 55X040 IRITYL TET DRATE (UNI	Moiety ient Name Z) (SALICYLIC ACID Ingredient BPV390UAP0) EAGY) Q8X) ) Q8X) ) Q2C32I) RASTEARATE (UNII I: 2968PHW8QP)	t Name		_	20 mg in 1 m

PEG-6 CAPRYL		PRIC GLYCE	RIDES (UNII: GO50W2HWO8)				
ZINC GLUCON							
EDETATE SOD	U) MUI	NII: MP1J8420	)LU)				
			RYLAMIDOPROPYLTRIMETHYL ACID 46:8:46; 1300000 MW)			co-	
MENTHOL (UN	II: L7T1	0EIP3A)					
CAPRYLOYL SA	ALICYL	IC ACID (UN	II: 5F7PJF6AA4)				
SODIUM BENZ	OATE	(UNII: OJ245F	E5EU)				
Packaging							
# Item Code		Packa	ge Description		ting Start Date		eting End Date
1	100 m Produc		Type 0: Not a Combination				
Marketin	ıg In	format	ion				
Marketin Categor		Applicat	ion Number or Monograph Citation	n Mar	keting Start Date	Mar	keting End Date
OTC Monograph	n Drug	M006					
Part 2 of	3						
LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE EFFACLAR CLARIFYING							
salicylic acid	solutio	on					
Product In	form	ation					
Route of Adı	minist	ration	TOPICAL				
<b>Active Ingr</b>	edier	nt/Active	Moiety				
		Ingre	dient Name		Basis of St	rength	Strength
SALICYLIC AC	ID (UNII	: 0414PZ4LP	Z) (SALICYLIC ACID - UNII:0414P	Z4LPZ)	SALICYLIC ACIE	)	5 mg in 1 mL
Inactive In	gredi	ents					
			Ingredient Name			St	rength
WATER (UNII: 0							
ALCOHOL (UNI							
PROPANEDIOL							
GLYCOLIC ACI	<b>D</b> (UNII	: 0WT12SX38	S)				
SODIUM HYDR							
CAPRYLOYL G			· · ·				
PHENOXYETH	ANOL (	UNII: HIE4922	2Z3T)				

BEN	BENZYL ALCOHOL (UNII: LKG8494WBH)							
PPG	PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)							
MEI								
BUT	BUTYLENE GLYCOL (UNII: 3XUS85KORA)							
Pa	Packaging							
	ltem				Marketi	ng Start	Mark	eting End
#	Code		Pack	age Description	Da	-		Date
1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product							
Ma	arketin	ig Infe	ormat	ion				
	Marketin	a	Applica	tion Number or Monograph	Marke	ting Start	Mar	ceting End
	Categor		••••	Citation		Date		Date
отс	Monograph	n Drug M	006					
Pa	rt 3 of	3						
DI	LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE EFFACLAR DUO ACNE TREATMENT benzoyl peroxide lotion							LAR
	.209. pere							
Pre	oduct In	format	tion					
Po	ute of Adr	ministra	tion	TOPICAL				
NU		mmstra	tion	TOPICAL				
Act	tive Ingr	edient	/Active	Moiety				
				•		Basis	of	Charles and h
			Ingr	edient Name		Streng	jth	Strength
	IZOYL PER W9WZ N9A0		inii: W9WZ	N9A0GM) (BENZOYL PEROXIDE -		BENZOYL PE	ROXIDE	55 mg in 1 mL
Ina	ctive In	gredier	nts					
				Ingredient Name				Strength
WA	TER (UNII: 0	)59QF0KO	0R)					
ISO	STEARYL A	LCOHOL	(UNII: Q62	L3OCO44Y)				
	ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y) GLYCERIN (UNII: PDC6A3C00X)							
GLY		II: PDC6A3						
			BCOOX)					
PEN	CERIN (UNI	LYCOL (U	3C0OX) JNII: 50C13					
PEN SILI	CERIN (UNI	<b>LYCOL</b> (U TJ7Z6XBU	3C0OX) JNII: 50C13 4)					
PEN SILI CAF	CERIN (UNI ITYLENE GI CA (UNII: ET BOMER (U	LYCOL (U TJ7Z6XBU NII: 0A5MI	8C0OX) JNII: 50C13 4) M307FC)					
PEN SILI CAP CAP	CERIN (UNI ITYLENE GI CA (UNII: ET BOMER (U PRYLOYL SA TASSIUM H	LYCOL (U TJ7Z6XBU NII: 0A5MI ALICYLIC YDROXID	3C0OX) JNII: 50C13 4) M307FC) ACID (UN DE (UNII: W	807PZG)				

			(UNII: 7FLD91C86K)			
EPII	LOBIUM ANG	GUSTI	FOLIUM FLOWER/LEAF/STEM EXTRACT (	JNII: 08H094218D)		
Pa	ckaging					
#	ltem Code	Package Description		Marketing Start Date	Marketing End Date	
1		20 mL Produ	in 1 TUBE; Type 0: Not a Combination			
		_				
Ma	arketing	g In	formation			
Ma	arketing Marketing Category	9	<b>formation</b> Application Number or Monograp Citation	h Marketing Start Date	Marketing End Date	
	Marketing	9	Application Number or Monograp			
	Marketing Category	9	Application Number or Monograp Citation			
	Marketing Category	9	Application Number or Monograp Citation			
отс	Marketing Category Monograph	Drug	Application Number or Monograp Citation M006			
отс	Marketing Category Monograph	Drug	Application Number or Monograp Citation			
отс	Marketing Category Monograph	g Drug g In	Application Number or Monograp Citation M006	Date		

# Labeler - L'Oreal USA Products Inc (002136794)

Establishment								
Name	Address	ID/FEI	<b>Business Operations</b>					
L'Oreal USA, Inc.		185931458	MANUFACTURE(49967-282)					

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Beauty Manufacturing Solutions Corp.		783200723	manufacture(49967-282)

Revised: 10/2024

L'Oreal USA Products Inc