

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE EFFACLAR DUO PLUS M
MULTI TARGET ACNE TREATMENT- salicylic acid liquid
L'Oreal USA Products Inc**

Drug Facts

Active ingredient

Salicylic acid 0.5%

Purpose

Acne treatment

Uses

- clears acne blemishes
- penetrates pores to control acne blemishes
- helps prevent new acne blemishes from forming

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 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

water, glycerin, dimethicone, isocetyl stearate, niacinamide, isopropyl lauroyl sarcosinate, silica, ammonium polyacryloyldimethyl taurate, oryza sativa (rice) starch, punica granatum pericarp extract, potassium cetyl phosphate, sorbitan oleate, zinc PCA, glyceryl stearate SE, isohexadecane, sodium hydroxide, myristyl myristate, 2-oleamido-1,3-octadecanediol, mannose, poloxamer 338, propanediol, hydroxyethoxyphenyl butanone, capryloyl salicylic acid, caprylyl glycol, vitreoscilla ferment, citric acid, trisodium ethylenediamine disuccinate, maltodextrin, xanthan gum, pentylene glycol, polysorbate 80, acrylamide/sodium acryloyldimethyltaurate copolymer, piroctone olamine, fragrance

Questions or comments?

1-888-LRP LABO

1-888-577-5226

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

EFFACLAR
DUO+M

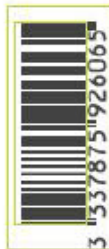


LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

INNOVATION

EFFACLAR
DUO+M

MULTI-TARGET
ACNE TREATMENT
SALICYLIC ACID
ACNE MEDICATION
Blackheads & Whiteheads
Stubborn Acne
Post-Acne Marks



DERMATOLOGIST TESTED

FOR SAFETY ON
ACNE-PRONE SKIN

WITH LA ROCHE-POSAY
THERMAL SPRING WATER

40 ml - 1.35 FL.OZ.
Made in France

FOR: Stubborn and recurring imperfections: blackheads, whiteheads, acne blemishes, and even stubborn acne. Also reduces the appearance of post-acne marks.

Improves appearance of:
- 66% Blackheads*
- 44% Blemishes*
* Clinical grading on 45 subjects, application once daily in the morning over 4 weeks.

Helps prevent recurrence of new acne blemishes & comedones. Gently exfoliates. Helps prevent future breakouts. Hydrating formula.

INGREDIENTS: Salicylic Acid: clears acne blemishes.
New Phelloderm: helps soothe skin & supports oil control.
Procerad™: occlusive anti-marks treatment helps prevent the appearance of post-acne marks.
Nibeinamide: helps fade appearance of dark marks and discoloration.
Lidil: helps to exfoliate skin.
Aqua Posae Filiformis: helps to durably restore skin's balance.

TEXTURE: Hydrating mattifying gel-cream. Non-greasy finish. Suitable for use under makeup. Non-comedogenic.

APPLICATION: Apply to the whole face morning and/or evening after cleansing skin.

TESTED ON ALL SKIN PHOTOTYPES.

INGREDIENTS: Salicylic Acid: clears acne blemishes.
New Phelloderm: helps soothe skin & supports oil control.
Procerad™: occlusive anti-marks treatment helps prevent the appearance of post-acne marks.
Nibeinamide: helps fade appearance of dark marks and discoloration.
Lidil: helps to exfoliate skin.
Aqua Posae Filiformis: helps to durably restore skin's balance.

TEXTURE: Hydrating mattifying gel-cream. Non-greasy finish. Suitable for use under makeup. Non-comedogenic.

APPLICATION: Apply to the whole face morning and/or evening after cleansing skin.

TESTED ON ALL SKIN PHOTOTYPES.



Clinical grading on 45 subjects, application once daily for 28 days. Mean score after applying these direct Effaclar-containing gel & Effaclar Duo+M once daily.

40ml/1.35 FL.OZ.

Distribution reserved to La Roche-Posay approved distributors.
L'Oréal USA, S.D. Inc., USA,
New York, NY 10001.
La Roche-Posay
Laboratoire Dermatologique
CD 86201 La Roche-Posay, France
TS 75000 St-Denis des Murs, France
www.laroche-posay.us

Drug Facts

Active Ingredient Purpose
Salicylic acid 0.5% Acne treatment

Uses

- for the treatment of acne
- clears acne blemishes
- penetrates pores to control acne blemishes
- helps prevent new acne blemishes from forming

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 day

Other information

- store at room temperature 68°-77°F
- protect from freezing

Inactive ingredients

water, glycerin, dimethicone, isocetyl stearate, niacinamide, isopropyl lauryl sarcosinate, silica, ammonium polyacryloyldimethyl taurate, oryza sativa (rice) starch, punica granatum pericarp extract, potassium cetyl phosphate, sorbitan oleate, zinc PCA, glyceryl stearate SE, isohexadecane, sodium hydroxide, myristyl myristate, 2-oleamido-1,3-octadecanediol, mannose, poloxamer 338, propanediol, hydroxyethoxyphenyl butanone, capryloyl salicylic acid, caprylyl glycol, vitreoscilla ferment, citric acid, triiodium ethylenediamine disuccinate, maledextrin, xanthan gum, pentylene glycol, polysorbate 80, acrylamide / sodium acryloyldimethyl taurate copolymer, proclene diamine, fragrance

Questions or comments?

1-888-LRP-LAB0 1-888-577-5225
Monday - Friday (a.m. - 5 p.m. EST)

203807139

Coda F.I.L. W00551321

C1 - Internal use

LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE EFFACLAR DUO

PLUS M MULTI TARGET ACNE TREATMENT

salicylic acid liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-926
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)		5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ISOPROPYL LAUROYL SARCOSINATE (UNII: LYR06W430J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (UNII: F01RIY4371)	
ORYZA SATIVA (RICE) STARCH (UNII: 4DGK8B7I3S)	
POMEGRANATE FRUIT RIND (UNII: RS999V57DU)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SORBITAN OLEATE (UNII: 06XEA2VD56)	
ZINC PCA (UNII: C32PQ86DH4)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
2-OLEAMIDO-1,3-OCTADECANEDIOL (UNII: 30D478BUNR)	
MANNOSE (UNII: PHA4727WTP)	
POLOXAMER 338 (UNII: F75JV2T505)	
PROPANEDIOL (UNII: 5965N8W85T)	
HYDROXYETHOXYPHENYL BUTANONE (UNII: TH7XI54W45)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
VITREOSCILLA LYSATE (UNII: 68DV8T89Y2)	
CITRIC ACID (UNII: 2968PHW8QP)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (120000 MPA.S AT 1%) (UNII: 5F4963KLHS)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-926-01	1 in 1 CARTON	05/14/2025	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-926-02	1 in 1 CARTON	05/14/2025	
2		3 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 Drug		M006	05/14/2025	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
COSMETIQUE ACTIVE PRODUCTION		282658798	manufacture(49967-926)