

**CETAPHIL GENTLE CLEAR TRIPLE-ACTION ACNE SERUM- salicylic acid solution  
Galderma Laboratories, L.P.**

*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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**Drug Facts**

**Active Ingredients**

Salicylic Acid 0.5%

**Purpose**

Acne treatment

**Uses**

For the management 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 treatment at a time. ■ avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

**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**

•**Sensitivity Test for New User:** Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow directions stated below. • 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.

**Inactive Ingredients**

WATER, GLYCERIN, COCO-CAPRYLATE/CAPRATE, GLUCONOLACTONE, PROPANEDIOL, SODIUM HYDROXIDE, SUCCINIC ACID, PANTHENOL, NIACINAMIDE, LYSOLECITHIN, SCLEROTIUM GUM, ZINC GLUCONATE, PULLULAN, XANTHAN GUM, PANTOLACTONE, CITRIC ACID, SILICA

**Questions or comments?**

1-866-735-4137

Distributed by:

Galderma Laboratories, L.P.

Fort Worth, TX 76177

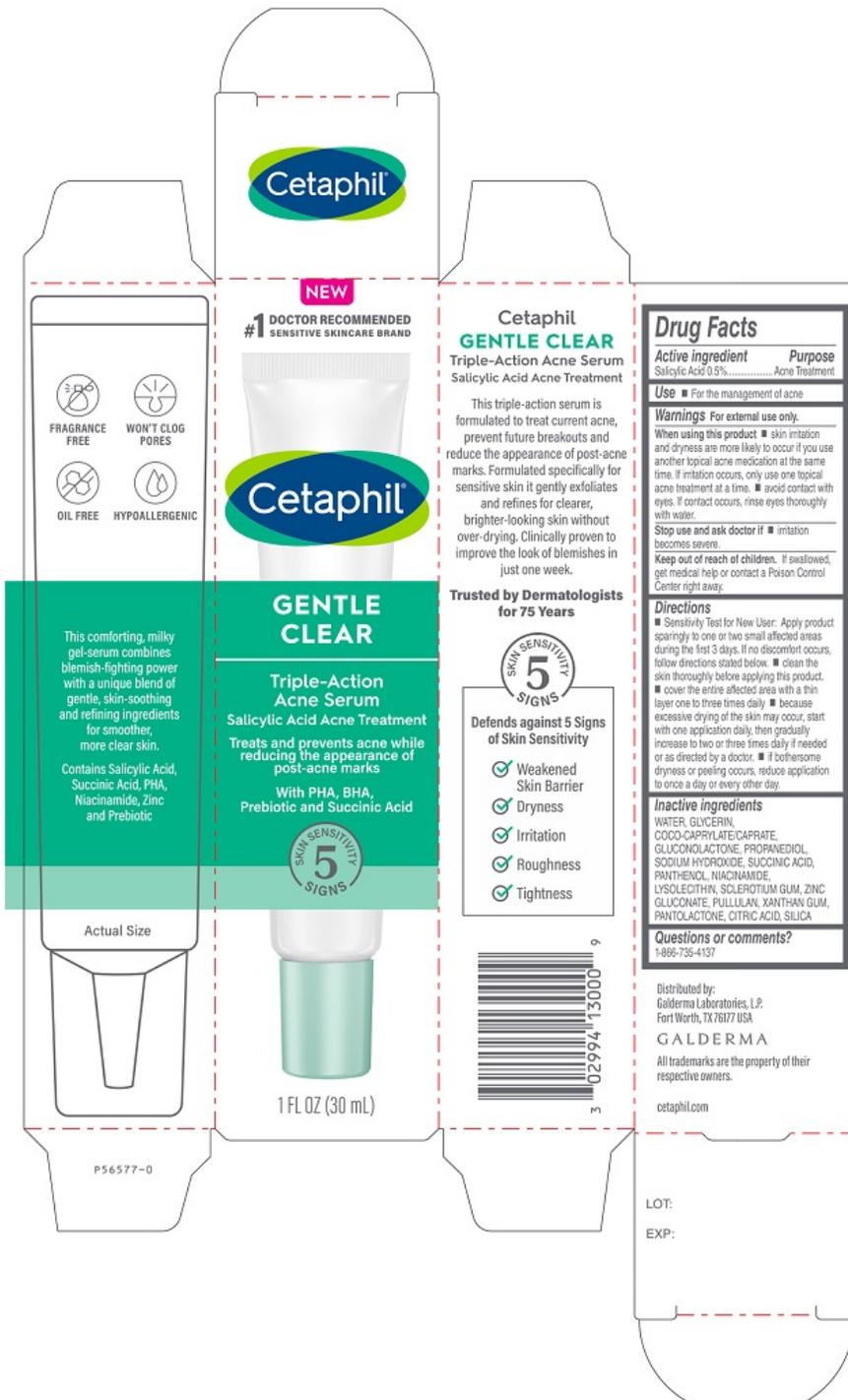
USA

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[cetaphil.com](http://cetaphil.com).

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**Principle Display Panel - 1 FL OZ Carton**



Cetaphil

NEW

#1 DOCTOR RECOMMENDED SENSITIVE SKINCARE BRAND

Cetaphil

GENTLE CLEAR

Triple-Action Acne Serum  
Salicylic Acid Acne Treatment  
Treats and prevents acne while reducing the appearance of post-acne marks  
With PHA, BHA, Prebiotic and Succinic Acid

5 SKIN SENSITIVITY SIGNS

- FRAGRANCE FREE
- WON'T CLOG PORES
- OIL FREE
- HYPOALLERGENIC

This comforting, milky gel-serum combines blemish-fighting power with a unique blend of gentle, skin-soothing and refining ingredients for smoother, more clear skin.  
Contains Salicylic Acid, Succinic Acid, PHA, Niacinamide, Zinc and Prebiotic

Actual Size

1 FL OZ (30 mL)

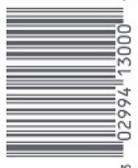
Cetaphil GENTLE CLEAR Triple-Action Acne Serum Salicylic Acid Acne Treatment

This triple-action serum is formulated to treat current acne, prevent future breakouts and reduce the appearance of post-acne marks. Formulated specifically for sensitive skin it gently exfoliates and refines for clearer, brighter-looking skin without over-drying. Clinically proven to improve the look of blemishes in just one week.

Trusted by Dermatologists for 75 Years

5 SKIN SENSITIVITY SIGNS

- Defends against 5 Signs of Skin Sensitivity
- ✔ Weakened Skin Barrier
  - ✔ Dryness
  - ✔ Irritation
  - ✔ Roughness
  - ✔ Tightness



**Drug Facts**

Active ingredient	Purpose
Salicylic Acid 0.5%	Acne Treatment

**Use** ■ For the management of acne

**Warnings** For external use only.  
When using this product ■ skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne treatment at a time. ■ avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.  
**Stop use and ask 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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**Questions or comments?**  
1-866-736-4137

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cetaphil.com

LOT:  
EXP:

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NEW

#1 Doctor Recommended  
Sensitive Skincare Brand

Cetaphil®

## **GENTLE CLEAR**

Triple-Action  
Acne Serum  
Salicylic Acid Acne Treatment

Treats and prevents acne while  
reducing the appearance of  
post-acne marks

**With PHA, BHA  
Prebiotic and Succinic Acid**

5 skin sensitivity signs

1 FL OZ (30 mL)

### **CETAPHIL GENTLE CLEAR TRIPLE-ACTION ACNE SERUM**

salicylic acid solution

#### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0299-4135
<b>Route of Administration</b>	TOPICAL		

#### **Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Salicylic Acid</b> (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	5 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Coco-Caprylate/Caprates</b> (UNII: 8D9H4QU99H)	
<b>Gluconolactone</b> (UNII: WQ29KQ9POT)	
<b>Propanediol</b> (UNII: 5965N8W85T)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Succinic Acid</b> (UNII: AB6MNQ6J6L)	
<b>Panthenol</b> (UNII: WW9CM0O67Z)	
<b>Niacinamide</b> (UNII: 25X51I8RD4)	
<b>Lysophosphatidylcholine, Soybean</b> (UNII: CQD833204Z)	
<b>Betasizofiran</b> (UNII: 2X51AD1X3T)	
<b>Zinc Gluconate</b> (UNII: U6WSN5SQ1Z)	
<b>Pullulan</b> (UNII: 8ZQ0AYU1TT)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Pantolactone, (R)-</b> (UNII: J288D7O0JS)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4135-00	1 in 1 CARTON	05/01/2022	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0299-4135-05	5 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	05/01/2022	

**Labeler** - Galderma Laboratories, L.P. (047350186)

## Establishment

Name	Address	ID/FEI	Business Operations
Fruit of The Earth, Inc.		080086802	manufacture(0299-4135)

Revised: 4/2022

Galderma Laboratories, L.P.