

## **PRO CLEAR FOAM- salicylic acid acne treatment liquid**

### **RELUMINS LABS LLC**

*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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#### **Active ingredient**

Salicylic acid 2.0%

#### **Purpose**

Acne medication

#### **Uses**

- 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**

- *Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the 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, glycolic acid, phelledendron amurense bark extract, pear juice ferment filtrate, rehmannia chinensis root extract, houttuynia cordata extract, melia azadirachta leaf extract, scutellaria baicalensis root extract, glycine soja (soybean) seed extract

# Package Labels - 2 fl oz (60 mL) - NDC 79061-042-01

## Bottle Label

RELUMINS

PRO CLEAR FOAM

Advanced Botanical Formula with 2% Salicylic Acid

Complete Facial Care For Blemish-Prone Skin

Penetrates Deep • Promotes Clear Skin

PROFESSIONAL SKIN CARE

2 fl oz (60 ml)

EXP:

LOT:

Relumins Labs

USA

183 Locust Ave

West Long Branch, NJ 07764

www.relumins.com

112.7mm

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**Drug Facts**

| Active ingredient      | Purpose         |
|------------------------|-----------------|
| Salicylic acid 2%..... | Acne medication |

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**Drug Facts (continued)**

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EXP :

LOT :

  
Relumins Labs  
USA  
183 Locust Ave  
West Long Branch, NJ 07764  
www.relumins.com

63.5mm

## Carton Label

RELUMINS

PRO CLEAR FOAM

Advanced Botanical Formula

Salicylic Acid Acne Treatment

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USA

183 Locust Ave

West Long Branch, NJ 07764

[www.relumins.com](http://www.relumins.com)

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Salicylic Acid Acne Treatment

Complete Facial Care  
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2 fl oz (60ml)

## PRO CLEAR FOAM

salicylic acid acne treatment liquid

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:79061-042 |
| <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           | 2 mg in 100 mL  |

**Inactive Ingredients**

| <b>Ingredient Name</b>                                     | <b>Strength</b> |
|--|-----------------|
| <b>WATER</b> (UNII: 059QF0KO0R)                            |                 |
| <b>GLYCOLIC ACID</b> (UNII: 0WT12SX38S)                    |                 |
| <b>PHELLODENDRON AMURENSE BARK</b> (UNII: PBG27B754G)      |                 |
| <b>PEAR JUICE</b> (UNII: F214DLA9BE)                       |                 |
| <b>REHMANNIA GLUTINOSA ROOT</b> (UNII: 1BEM3U6LQQ)         |                 |
| <b>HOULTUYNIA CORDATA FLOWERING TOP</b> (UNII: RH041UUZ22) |                 |
| <b>AZADIRACHTA INDICA LEAF</b> (UNII: HKY915780T)          |                 |
| <b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)     |                 |
| <b>SOYBEAN</b> (UNII: L7HT8F1ZOD)                          |                 |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                           | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 1        | NDC:79061-042-01 | 1 in 1 CARTON  | 05/21/2021                  |                           |
| 1        |                  | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product |                             |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part333D  | 05/21/2021                  |                           |

**Labeler** - RELUMINS LABS LLC (081506626)**Establishment**

| <b>Name</b>              | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|--------------------------|----------------|---------------|----------------------------|
| COSMESTHETIC LABS. CORP. |                | 725862577     | manufacture(79061-042)     |