# SKINMD LABORATORIES PURE WHITENOL SERUM- tranexamic acid cream Revires co Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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#### ACTIVE INGREDIENT

Active ingredients: Tranexamic acid 0.1%

### INACTIVE INGREDIENT

Inactive ingredients:

Water Butylene Glycol Glycerin, Octyldodecyl Myristate Hydrogenated Poly(C6-14 Olefin) Limnanthes Alba (Meadowfoam) Seed Oil, Mineral Oil, Borago Officinalis Seed Oil, Rhodiola Sachalinensis Extract, Morus Alba Root Extract, Pentylene Glycol, Polysorbate 60, Glyceryl Stearate SE, Stearic Acid, Hydroxypropyl Bispalmitamide MEA, Cyclopentasiloxane, Dimethicone, Sorbitan Sesquioleate, Sorbitan Stearate, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Glyceryl Stearate, PEG-100 Stearate, Cyclohexasiloxane, Dextrin, Lecithin, Isohexadecane, Caprylyl Glycol, Tocopheryl Acetate, 4-Butylresorcinol, Trehalose, Arginine, Polysorbate 80, Squalane, Sodium Hyaluronate, Cetearyl Alcohol, Carbomer, BHT, Disodium EDTA, Fragrance(Parfum)

#### **PURPOSE**

Purpose: Skin Whitening

#### WARNINGS

Warnings:

1. Discontinue use if the following symptoms occur. If symptoms are extreme consult a dermatologist.

1) Symptoms such as red dots, swollenness, itching, stimulation during use. 2) Symptoms such as the ones mentioned in 1) occur on the applied area. 2. Do not apply to parts of the skin that have rashes, are cut, or are infected. 3. Directions for storage and handling. 1) The lid must be closed after use. 2) Keep out of reach of babies and children. 3) Store in a cool and dry place and avoid exposure to direct sunlight.

### KEEP OUT OF REACH OF CHILDREN

Keep out of reach of babies and children.

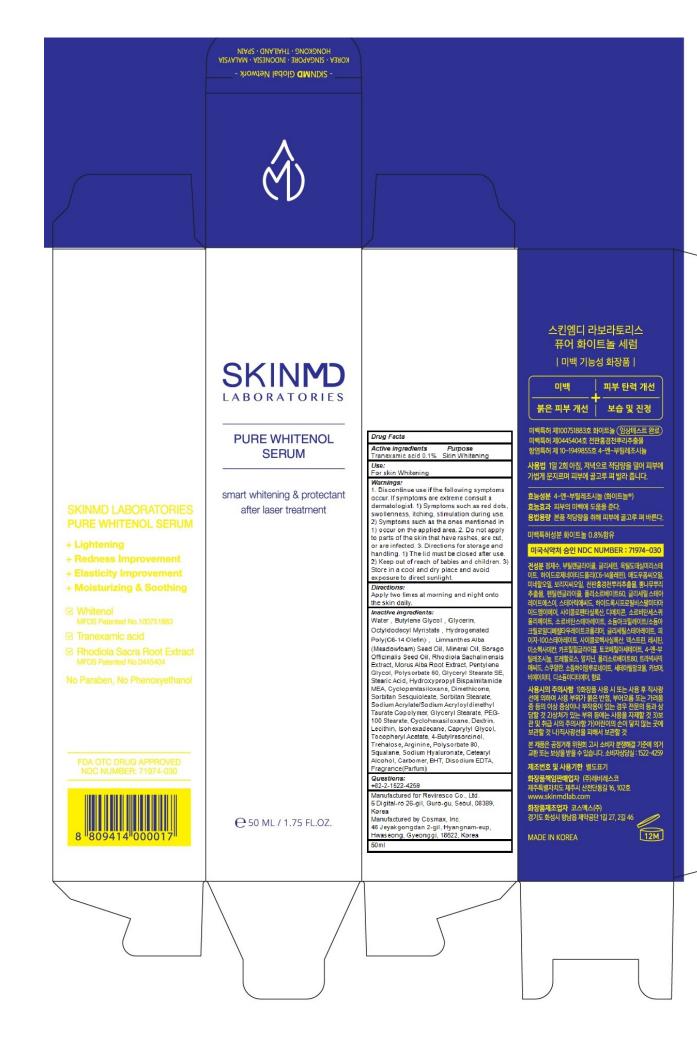
Uses

Uses: For skin Whitening

### **Directions**

Directions: Apply two times at morning and night onto the skin daily.

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



### SKINMD LABORATORIES PURE WHITENOL SERUM

tranexamic acid cream

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71974-030

Route of Administration TOPICAL

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

| 2 1.101019      |                   |          |
|-----------------|-------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
|                 |                   |          |

Tranexamic acid (UNII: 6T84R30KC1) (TRANEXAMIC ACID - UNII:6T84R30KC1) Tranexamic acid 0.05 g in 50 mL

### **Inactive Ingredients**

| mactive ingredients                |          |
|------------------------------------|----------|
| Ingredient Name                    | Strength |
| Water (UNII: 059QF0KO0R)           |          |
| Butylene Glycol (UNII: 3XUS85K0RA) |          |

### **Packaging**

| a chagnig            |  |                         |                       |
|----------------------|--|-------------------------|-----------------------|
| # Item Code          | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
| NDC:71974-030-<br>02 | 1 in 1 CARTON  | 12/01/2017              |                       |
| NDC:71974-030-       | 50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product |                         |                       |

# **Marketing Information**

| 8                     |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other |  | 12/0 1/20 17         |                    |
|                       |  |                      |                    |

# Labeler - Revires co Co., Ltd. (693937110)

## Registrant - Reviresco Co., Ltd. (693937110)

| Establishment |         |           |                        |
|---------------|---------|-----------|------------------------|
| Name          | Address | ID/FEI    | Business Operations    |
| Cosmax, Inc.  |         | 689049693 | manufacture(71974-030) |

Revised: 12/2019 Reviresco Co., Ltd.