

SIERO TURNOVER 21 CREA M PACK- dimethicone cream
JNG KOREA CO.,LTD.

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.

ACTIVE INGREDIENT

Active ingredients: Dimethicone 4.0%

INACTIVE INGREDIENT

Inactive ingredients: Water, Glycerin, Dipropylene Glycol, Butylene Glycol, Stearic Acid, Isopropyl Myristate, Cetyl Alcohol, Gluconolactone, Glyceryl Stearate, PEG-100 Stearate, Glyceryl Stearate SE, Portulaca Oleracea Extract, Ammonium Acryloyldimethyltaurate/VP Copolymer, Phenoxyethanol, Carbomer, Chlorphenesin, Potassium Hydroxide, Lactobionic Acid, Citrus Aurantium Dulcis (Orange) Oil, t-Butyl Alcohol, Citrus Aurantifolia (Lime) Oil, Citrus Grandis (Grapefruit) Peel Oil, Disodium EDTA, Citrus Limon (Lemon) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Pelargonium Graveolens Flower Oil, Ocimum Basilicum (Basil) Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Salvia Sclarea (Clary) Oil

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings: - Keep away from direct sunlight and high temperature. - Use only at night. - For external use only. Avoid contact with eyes. Discontinue use if signs of irritation or rashes appear. Replace the cap after use.

KEEP OUT OF REACH OF CHILDREN

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Uses

Uses: A home peeling cream pack that makes your skin that is dry and flaky from dead skin smooth and moisturized while sleeping pH 4.2 mildly acidic sleeping cream pack contains gluconolactone, a type of PHA, and lactobionic acid to take care of the dead skin cells gently at night by shortening their turnover cycle to 21 days for a healthy and smooth skin texture.

Directions

Directions: Before going to bed, apply to the entire face as the last step of skin care and let it absorb. (Do not use during the day.)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | Dimethicone | 2.0 g in 50 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------|----------|
| Water (UNII: 059QF0KO0R) | |
| Glycerin (UNII: PDC6A3C0OX) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71472-010-02 | 1 in 1 CARTON | 06/01/2017 | |
| 1 | NDC:71472-010-01 | 50 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 final | part347 | 06/01/2017 | |

Labeler - JNG KOREA CO.,LTD. (557796103)

Registrant - JNG KOREA CO.,LTD. (557796103)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---------------------|
| JNG KOREA CO.,LTD. | | 557796103 | relabel(71472-010) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| Hankook Cosmetics Manufacturing Co.,Ltd_Eumseong Factory | | 688235645 | manufacture(71472-010) |

Revised: 6/2017

JNG KOREA CO.,LTD.