

**EVENING MOISTURIZER- salicylic acid cream
SGII, INC.**

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.

Evening Moisturizer

Active Ingredient

Salicylic Acid 1%

Purpose

Salicylic Acid 1%.....Acne Treatment

Uses

For the treatment of acne

Warnings

For External Use Only

Keep Out Of Eyes

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

Inactive Ingredients

Sodium Hyaluronate, Panthenol, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Arginine, Dimethicone, Ceteth-10 Phosphate, Dicaprylyl Phosphate, Hydrolyzed Caesalpinia Spinosa Gum, Phenoxyethanol, Cetyl Palmitate, Caprylyl Glycol, Sorbitan Palmitate, Propylene Glycol, Butylene Glycol, Caesalpinia Spinosa Gum, Ethylhexylglycerin, Hexylene Glycol, Bisabolol, Tetrasodium EDTA, Potassium Sorbate, Sodium Benzoate, Urea*, Glucosamine HCl, Sodium Metabisulfite, Citric Acid, Parfum/Fragrance. *synthetic



SeneGence
Evening Moisturizer
Oily to Acne
GOLD: PMS 871 C
BLUE: PMS Reflex Blue C
 White Label
 LBW3033A

4.1562"

Top

Drug Facts

| Active Ingredient | Purpose |
|-------------------|----------------|
| Salicylic Acid 1% | Acne treatment |

Uses
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Warnings
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Keep out of eyes.

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SeneGence®
Evening Moisturizer
 OILY TO ACNE
 1% Salicylic Acid Acne Treatment
 SenePlex+®
 1 fl. oz. / 30 mL

PEEL HERE FOR DRUG FACTS.

LBW3033A/REV A

2.5"

1/8" corner radius

Top Back

Drug Facts (continued)

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

Inactive Ingredients Aqua/Water/Eau, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Glycerin, Glycereth-26, Avocado (Persea Gratissima) Oil, Jojoba (Simmondsia Chinensis) Seed Oil, Shea (Butyrospermum Parkii) Butter, Olive (Olea Europaea) Fruit Oil, Cetearyl Oliviate, Sorbitan Oliviate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Cucumber (Cucumis Sativus) Extract, Willow Herb (Epilobium Angustifolium) Extract, Kelp (Laminaria Digitata) Extract, Yeast (Saccharomyces Cerevisiae) Extract, Ginger (Zingiber Officinale) Root Extract, Seaweed (Corallina Officinalis) Extract, Orchid (Orchis Morio) Flower Extract, Tetrapeptide-17.

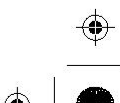
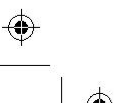
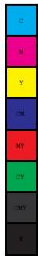
Base

Drug Facts (continued)

Inactive Ingredients (continued) Sodium Hyaluronate, Panthenol, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Arginine, Dimethicone, Ceteth-10 Phosphate, Dicityl Phosphate, Hydrolyzed Caesalpinia Spinosa Gum, Phenoxylethanol, Cetyl Palmitate, Caprylyl Glycol, Sorbitan Palmitate, Propylene Glycol, Butylene Glycol, Caesalpinia Spinosa Gum, Ethylhexylglycerin, Hexylene Glycol, Bisabolol, Tetrasodium EDTA, Potassium Sorbate, Sodium Benzoate, Urea*, Glucosamine HCl, Sodium Metabisulfite, Citric Acid, Parfum/Fragrance. *synthetic

Dist. By: SeneGence®
 19651 Alter, Foothill Ranch, CA 92610
 Made in the USA w/ Global Materials

- die line
- text limit line
- bleed limit line
- release varnish





EVENING MOISTURIZER

salicylic acid cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72644-635 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | 1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERETH-26 (UNII: NNE56F2N14) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| SORBITAN OLIVATE (UNII: MDL271E3GR) | |
| EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D) | |
| GINGER (UNII: C5529G5JPQ) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| SORBITAN MONOPALMITATE (UNII: 77K6Z421KU) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| CETETH-10 PHOSPHATE (UNII: 4E05O5N49G) | |
| CETYL PALMITATE (UNII: 5ZA2S6B08X) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| AVOCADO OIL (UNII: 6VNO72PFC1) | |
| CETEARYL OLIVATE (UNII: 58B69Q84JO) | |
| CUCUMBER JUICE (UNII: 61845009SP) | |
| AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG) | |
| LAMINARIA DIGITATA (UNII: 15E7C67EE8) | |
| YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U) | |
| CORALLINA OFFICINALIS (UNII: 4004498D06) | |
| ANACAMPTIS MORIO FLOWER (UNII: PT2C4RA48D) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| ARGININE (UNII: 94ZLA3W45F) | |
| DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |

| | |
|---|--|
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY) | |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C) | |
| FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| PANTHENOL (UNII: WV9CM0067Z) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| LEVOMENOL (UNII: 24WE03BX2T) | |
| UREA (UNII: 8W8T17847W) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72644-635-01 | 30 g in 1 BOTTLE; Type 0: Not a Combination Product | 09/16/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part358H | 09/16/2020 | |

Labeler - SGII, INC. (070096792)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| 220 LABORATORIES INC | | 783247950 | manufacture(72644-635) |