

**CELLADIX SEBUM REBALANCING RX 131 AMPOULE- niacinamide,
adenosine solution/ drops
2359 US INC**

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.

83490-601 Celladix Sebum Rebalancing Rx 131 Ampoule

Active Ingredients

Niacinamide 2.0%
Adenosine 0.04%

Purposes

Niacinamide 2.0% ----- Skin protectant
Adenosine 0.04% ----- Astringent

Uses

For skin barrier repair, perfect for oily skin

Warnings

For external use only.

Warnings

Do not use it on open wounds and sensitive skin.

Warnings

Keep out of reach of children.

Warnings

Stop use and ask a doctor If there are any abnormal symptoms or side effects such as red spots, swelling, or itching during or immediately after use

Warnings

Directions

After cleansing or toning, take an appropriate amount of the ampoule and gently spread it over the face for absorption

Inactive Ingredients

Water, Dipropylene Glycol, Butylene Glycol, Glycereth-26, Niacinamide, Glycerin, Betain, Phytosterols, Ceramide NP, Squalane, Lauric Acid, Arachidic Acid, Behenic Acid, Beta-Glucan, Paulownia Tomentosa Leaf Extract, Cinnamomum Cassia Bark Extract, Cinnamomum Japonicum Leaf Extract, Cinnamomum Camphora (Camphor) Leaf Extract, Laurus Nobilis Leaf Extract, Coriandrum Sativum (Coriander) Extract, Eucalyptus Globulus Leaf Extract, Scutellaria Baicalensis Root Extract, Machilus Thunbergii Branch Extract, 1,2-Hexanediol, Polyglyceryl-10 Laurate, Polyglyceryl-10 Myristate, Hydroxyacetophenone, Panthenol, Adenosine, Disodium EDTA, Sodium Hyaluronate, Xanthan Gum, Sodium Polyacrylate, Ethylhexylglycerin, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Lavandula Hybrida Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Amyris Balsamifera Bark Oil, Ocimum Basilicum (Basil) Oil, Limonene, Linalool

Label

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Keep out of reach of children.

Avoid storing in direct sunlight.

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Distributed by 2359 US Inc.

1810 E Sahara Ave. #100 Las Vegas, NV 89104

Made in Korea

CELLADIX SEBUM REBALANCING RX 131 AMPOULE

niacinamide, adenosine solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83490-601 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4) | NIACINAMIDE | 2 g in 100 mL |
| ADENOSINE (UNII: K72T3FS567) (ADENOSINE - UNII:K72T3FS567) | ADENOSINE | 0.04 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LAURIC ACID (UNII: 1160N9NU9U) | |
| BEHENIC ACID (UNII: H390488X0A) | |
| CINNAMOMUM CAMPHORA LEAF (UNII: A0TKE4ZO0S) | |
| BAY LEAF (UNII: W5OY3M85RF) | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| BETAINE (UNII: 3SCV180C9W) | |
| ARACHIDIC ACID (UNII: PQB8MJD4RB) | |
| PAULOWNIA TOMENTOSA LEAF (UNII: D175ZR7P0C) | |

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|--|
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) |
| POLYGLYCERYL-10 MYRISTATE (UNII: Y9WL8QN3ZB) |
| PANTHENOL (UNII: WW9CM0067Z) |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) |
| XANTHAN GUM (UNII: TTV12P4NEE) |
| AMYRIS BALSAMIFERA OIL (UNII: I1BJ961J2E) |
| LAVANDIN OIL (UNII: 9RES347CKG) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| CERAMIDE NP (UNII: 4370DF050B) |
| SQUALANE (UNII: GW89575KF9) |
| POLYGLYCERYL-10 LAURATE (UNII: MPJ2Q8W8G) |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) |
| CORIANDRUM SATIVUM WHOLE (UNII: 740M8BF6EF) |
| EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6) |
| SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S) |
| BASIL OIL (UNII: Z129UMU8LE) |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) |
| ORANGE OIL (UNII: AKN3KSD11B) |
| WATER (UNII: 059QF0KO0R) |
| LAVENDER OIL (UNII: ZBP1YXW0H8) |
| GLYCERETH-26 (UNII: NNE56F2N14) |
| CHINESE CINNAMON (UNII: W54CQ062KM) |
| MACHILUS THUNBERGII BRANCH (UNII: 301F5K1I0R) |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) |
| BERGAMOT OIL (UNII: 39W1PKE3JI) |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:83490-601-01 | 20 mL in 1 AMPULE; Type 0: Not a Combination Product | 05/24/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 05/24/2023 | |

Labeler - 2359 US INC (118974080)

Registrant - 2359 US INC (118974080)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

isamogu Inc.

695695834

manufacture(83490-601)

Revised: 3/2023

2359 US INC