

LEADERS MEDIU CALMING PEPPERMINT PACK- allantoin gel
SANSUNG LIFE & SCIENCE 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 Ingredient: Allantoin 0.51%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Phaseolus angularis seed powder, Butylene Glycol, Kaolin, Bentonite, Magnesium aluminum silicate, PVP, Cellulose, Caramel, Chromium Oxide greens, Betaine, Titanium dioxide, Aloe barbadensis leaf water, Daucus carota sativa (carrot) root extract, Cucurbita pepo (pumpkin) fruit extract, Disodium EDTA, Mentha piperita (peppermint) oil, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Phenoxyethanol, Chlorphenesin

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings: For external use only. Avoid contact with eyes. Not for human consumption. Discontinue use if irritation occurs. If irritation persists, consult a physician.

Use immediately after opening. Store in cool and dry place. Keep out of reach of children.

KEEP OUT OF REACH OF CHILDREN

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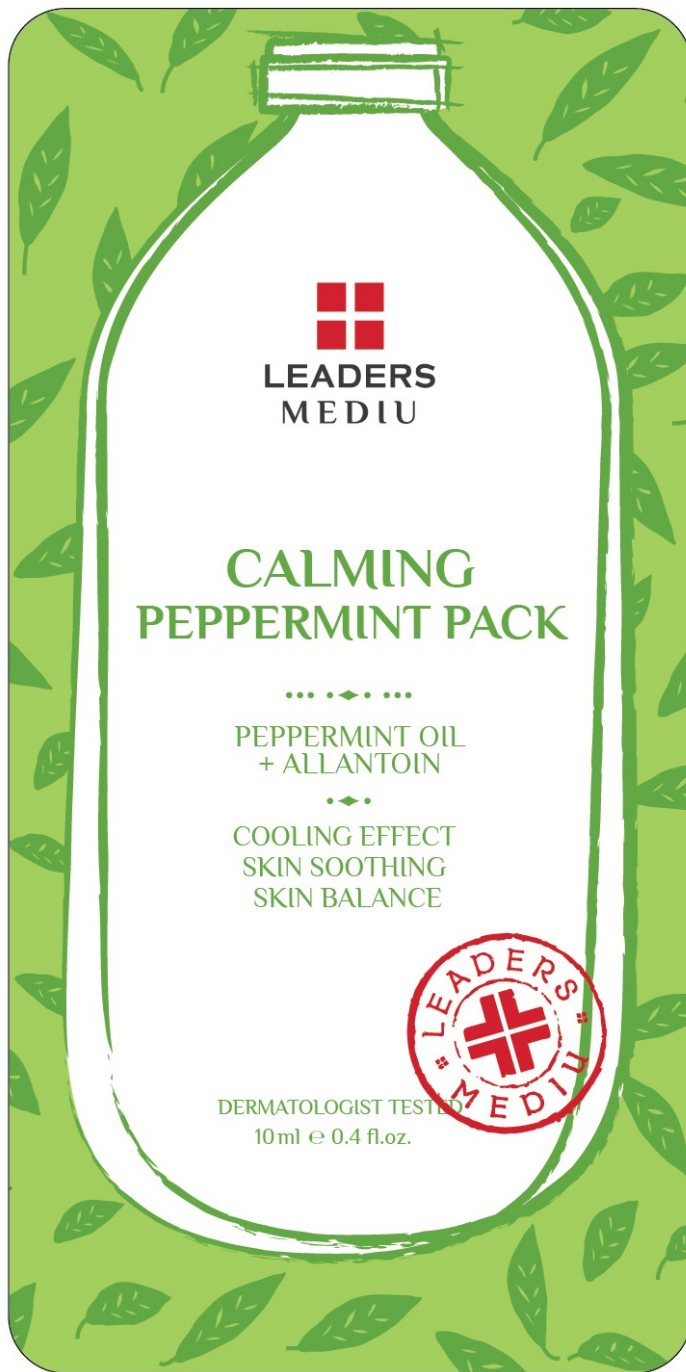
Directions

Directions: After cleansing face, apply a thin layer of the Wash-Off Pack on the face, leaving out the area around eyes and mouth. Leave on for 5-10 minutes then wash off with tepid water. *Suggested use is 2-3 times a week

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LEADERS MEDIU CALMING PEPPERMINT PACK

allantoin gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69424-450 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| Allantoin (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | Allantoin | 51.0 mg in 10 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------|----------|
| Water (UNII: 059QF0KO0R) | |
| ADZUKI BEAN (UNII: 31GYU1X0FP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69424-450-01 | 10 mL in 1 CELLO PACK; 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 | 12/01/2015 | |

Labeler - SANSUNG LIFE & SCIENCE CO., LTD. (689524929)**Registrant** - SANSUNG LIFE & SCIENCE CO., LTD. (689524929)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|---------|-----------|------------------------|
| SANSUNG LIFE & SCIENCE CO., LTD. | | 689524929 | manufacture(69424-450) |

Revised: 2/2016

SANSUNG LIFE & SCIENCE CO., LTD.