CLARA 1984- dimethicone cream CLARA GROUP

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: DIMETHICONE 1.0%

INACTIVE INGREDIENT

Inactive Ingredients:

Vaseline, Sophora Japanese, Myrobalan, Ginger, Madder, Akanthopanax, Gomphocarpus, Zigadenus, Liquidambar, Aristolochia, Anacamptis, Cinnamon, Saffron powder, Wild rose, Peppermint, violet, Olive

PURPOSE

Purpose: Skin Moisturizing, Protection

WARNINGS

Warnings:

During the summer time store in refrigerator. and Place product at room temperature for else seasons. / Not recommended for children under 4 years. / Expiration period: 2 years

KEEP OUT OF REACH OF CHILDREN

Not recommended for children under 4 years.

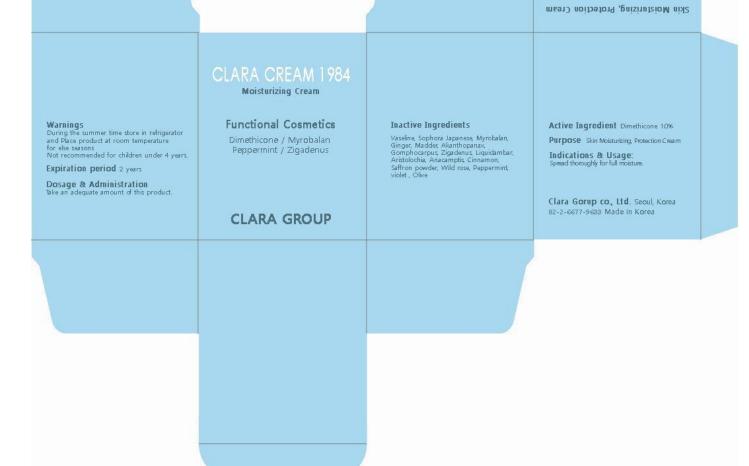
INDICATIONS & USAGE

Indications and Usage: Spread thoroughly for full moisture.

DOSAGE & ADMINISTRATION

Dosage and Administration: Take an adequate amount of this product.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



| CLARA 1984 | | | | | | |
|--|----------------|--------------|--------------------------|--|-----------------|--|
| limethicone cream | | | | | | |
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| Product Information | | | | | | |
| Product T ype | HUMAN OTC DRUG | Item Code (S | Item Code (Source) | | NDC:69404-010 | |
| Route of Administration | TOPICAL | | | | | |
| | | | | | | |
| | | | | | | |
| Active Ingredient/Active M | oiety | | | | | |
| Ingredient Name | | | Basis of Strength | | Strength | |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | | | DIMETHICONE | | 0.5 mg in 50 mL | |

| Ingredient Name | | | | | Strength | |
|-----------------------------|--|----------------------|----------------------|--------------------|--------------------|--|
| Cinnamon (UNII: 5S29HWU6QB) | | | | | | |
| | | | | | | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | Package Description | Marketing Start Date | | Marketing End Date | | |
| NDC:69404-010-01 | 50 mL in 1 CARTON | | | | | |
| | | | | | | |
| | | | | | | |
| Marketing Info | rmation | | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | | Marketing End Date | |
| | | | | | | |

Labeler - CLARA GROUP (689060172)

Registrant - CLARA GROUP (689060172)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| CLARA GROUP | | 689060172 | manufacture(69404-010) |

Revised: 1/2015

CLARA GROUP