

OATMEAL SKIN RELIEF CALMING . 8OZ- dimethicone lotion
China Ningbo Shangge Cosmetic Technology Corp.

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.

Oatmeal daily moisturizing lotion (8 oz.)

Active Ingredient

Dimethicone 1.3%

Purpose

Skin protectant

Ⓜ**Keep out of reach of children.**Ⓜ If swallowed, get medical help or contact a Poison Control Center immediately.

Ⓜ**Use**

ⓂHelp prevent and temporarily protects chafed, chapped, or cracked skin.

Warnings ⓂFor external use only.

When using this product Ⓜavoid contact with eyes. In case of eye contact, flush with water.

Do not use on

Deep or puncture wounds

Animal bites

Serious burns

Stop use and ask a doctor if conditions worsens. Symptoms last more than 7 days or clear up and occur again within a few days.

Ⓜ**Directions**Ⓜ apply liberally as often as needed.

Ⓜ**Other Information**Ⓜ store at room temperature.

Ⓜ**Inactive Ingredients**

Water, Petrolatum, Cetyl Alcohol, Glyceryl Stearate, Propylene Glycol, Glycerin, Stearyl Alcohol, PEG-100 Stearate, Polyacrylamide, DMDM Hydrantoin, Isopropyl Myristate, Fragrance, C13-14 Isoparaffin, Laureth-7, Avena Sativa (Oat) Kernel Extract, Disodium EDTA, Methylparaben, Propylparaben

XtraCare[®]

with cooling action

Oatmeal

**Skin Relief
Calming Lotion**

dimethicone skin protectant



provides immediate
and lasting moisture
relief for itchy,
extra dry skin

NET WT 8 OZ (227 g)

Drug Facts

| | |
|--|-----------------|
| Active ingredient | Purpose |
| Dimethicone 1.3% | Skin protectant |
| Use Help prevent and temporarily protects chafed, chapped, or cracked skin. | |
| Warnings For external use only. | |
| When using this product avoid contact with eyes. In case of eye contact, flush with water. | |
| Do not use on ● deep or puncture wounds ● animal bites ● serious burns | |
| Stop use and ask a doctor if condition worsens. Symptoms last more than 7 days or clear up and occur again within a few days. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately. | |
| Directions apply liberally as often as needed. | |
| Other information Store at room temperature. | |
| Questions/Comments? 1-855-345-5575 | |
| Inactive ingredients Water, Petrolatum, Cetyl Alcohol, Glyceryl Stearate, Propylene Glycol, Glycerin, Stearyl Alcohol, PEG-100 Stearate, Polyacrylamide, DMDM Hydantoin, Isopropyl Myristate, Fragrance, C13-14 Isoparaffin, Laureth-7, Avena Sativa (Oat) Kernel Extract, Disodium EDTA, Methylparaben, Propylparaben. | |



DISTRIBUTED BY:
REJOICE INTERNATIONAL INC.
NORTHVILLE, MI 48168, USA
MADE IN CHINA

OATMEAL SKIN RELIEF CALMING . 8OZ

dimethicone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58503-118 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 3 g in 227 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| LAURETH-7 (UNII: Z95S6G8201) | |
| MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ) | |
| POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I) | |

| | |
|--|--|
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) | |
| CETYL STEARATE (UNII: 06R15UQA7L) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| WATER (UNII: 059QF0KO0R) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| STEARYL ALCOHOL (UNII: 2KR89I4HIY) | |
| OAT KERNEL OIL (UNII: 3UVP41R77R) | |
| DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:58503-118-01 | 227 g in 1 BOTTLE; Type 0: Not a Combination Product | 03/07/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 03/07/2019 | |

Labeler - China Ningbo Shangge Cosmetic Technology Corp. (529287434)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| China Ningbo Shangge Cosmetic Technology Corp. | | 529287434 | manufacture(58503-118) |

Revised: 3/2019

China Ningbo Shangge Cosmetic Technology Corp.