

NANOMIX BODY CARE- dimethicone lotion
NANOPOLY 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: Dimethicone 1.2%

INACTIVE INGREDIENT

Inactive Ingredient: Water, Glycerin, Cetyl Ethylhexanoate, Urea, Caprylic/Capric Triglyceride, Pentylene Glycol, Dimethicone, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Zea Mays (Corn) Starch, Propanediol, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Arachidyl Alcohol, Behenyl Alcohol, Olea Europaea (Olive) Fruit Oil, Caprylyl Glycol Fragrance(Parfum), Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Arachidyl Glucoside, Isohexadecane, Arginine, Xanthan Gum, Carbomer, Polysorbate, Colloidal Silver, Serine

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings:

1. In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist.
- 1) In case of having problems such as red rash, swollenness, itching, stimulation during usage.
- 2) In case of having the same symptoms above on the part you put this product on by direct sunlight.
2. You are banned to use it on the part where you have a scar, eczema, or dermatitis.
3. In case of getting it into your eyes, you have to wash it immediately.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:

Keep out of reach of babies and children.

INDICATIONS AND USAGE

Indication and usage:

Avoid to direct sunlight.

Do not keep in hot(higer 40C) or cold(below 0C).

Rotate the cap of pump counterclockwise and then rise the cap, press the pump cap to use the lotion.

DOSAGE AND ADMINISTRATION

Dosage and administration:

Apply after washing body.

Take a small amount of lotion about 2g onto the fingertips and gently massage over the entire body.

Especially use the lotion over dry or itchy part 2-3 times per day.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



| NANOMIX BODY CARE | | | |
|--------------------------------|----------------|---------------------------|---------------|
| dimethicone lotion | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54170-110 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | Dimethicone | 4.8 mg in 400 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------|----------|
| Water (UNII: 059QF0KO0R) | |
| Glycerin (UNII: PDC6A3C0OX) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:54170-110-01 | 400 mL in 1 CARTON | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 06/01/2013 | |

Labeler - NANOPOLY CO., LTD. (687162537)**Registrant** - NANOPOLY CO., LTD. (687162537)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---------------------|
| NANOPOLY CO., LTD. | | 687162537 | repack(54170-110) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| COSMAX INC. | | 689019313 | manufacture(54170-110) |

Revised: 8/2013

NANOPOLY CO., LTD.