

NURTURE BARRIER- dimethicone cream

Rise Global Products

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

Purpose

Dimethicone 5%.....Skin Protectant

☐ Long-lasting nourishing formula that helps prevent dry, cracked skin.

- Non-Sensitizing
- Non-Allergenic

☐ Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

☐ Uses

Temporarily protects and helps relieve chapped or cracked skin.

Beneficial for face, hands, body and legs

☐ Warnings

For External Use Only

Do Not Use

- on deep or puncture wounds
- on animal bites
- on serious burns

☐ When using this product

- Do not get into eyes

☐ Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days

☐ Directions

- Cleanse skin with Nurture(TM) Foaming Body Cleanser
- Apply cream liberally to affected area as needed

☐ Other Information

- Protect from freezing
- Avoid excessive heat

☐ Inactive Ingredients

Water, canola oil, aloe barbadensis leaf juice, PEG-8, glyceryl stearate, glycerin, propylene glycol, cyclomethicone, cetyl alcohol, stearic acid, triethanolamine, PEG-100 Stearate, allantoin, pyridoxine HCL, niacinamide, glycine, L-aurine, N-acetyl-L-cysteine, methylsulfonylmethane, L-proline, vanillin, citrus aurantium dulcis (orange) peel oil, citrus tangerina (tangerine) peel oil, citrus grandis (grapefruit) peel oil, dimethicone/vinyl dimethicone crosspolymer, citric acid, urea, polymethylsiloxane, ammonium acryloyldimethyl taurate/vp copolymer, phenoxyethanol, DMDM hydantoin.



858655003033

Nurture® Barrier Cream

Nurture® nourishes skin cells with essential vitamins and natural ingredients while NurturGuard™ helps protect against harsh environments.

Drug Facts

Active Ingredient	Purpose
Dimethicone 5%.....	Skin Protectant

Uses • For the treatment and/or prevention of diaper rash • Temporarily protects and helps relieve chapped or cracked skin

Warnings**For External Use Only**

Do Not Use • on deep or puncture wounds • on animal bites • on serious burns

When using this product • Do not get into eyes

Stop use and ask a doctor if • Condition worsens

• Symptoms last for 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 right away

Directions • Cleanse skin with Nurture™ Foaming Body Cleanser • Apply cream liberally to affected area as needed

Other Information • Protect from freezing
• Avoid excessive heat

Inactive Ingredients Water, Persea Gratissima (Avocado) Oil, Aloe Barbadensis Leaf Juice, PEG-8, Glyceryl Stearate, Glycerin, Propylene Glycol, Cyclomethicone, Cetyl Alcohol, Stearic Acid, Triethanolamine, PEG-100 Stearate, Allantoin, Pyridoxine HCL, Niacinamide, Glycine, L-Taurine, N-acetyl-L-Cysteine, Methylsulfonylmethane, L-Proline, Vanillin, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Tangerina (Tangerine) Peel Oil, Citrus Grandis (Grapefruit) Peel Oil, Urea, Ammonium Acryloyldimethyl Taurate/VP Copolymer, Citric Acid, Dimethicone/Vinyl Dimethicone Crosspolymer, Polymethylsilsesquioxane, Phenoxyethanol, DMDM Hydantoin.

ROOM NO

NAME

**Barrier Cream**

Long-lasting nourishing formula that helps prevent dry, cracked skin

- Non-Sensitizing
- Non-Allergenic

Distributed by
Rise Global Products LLC
3833 Franklin Ave. Waco, Texas 76710
REORDER 21200

Not tested on Animals
Made in the USA
www.riseglobalproducts.com

PROTECT
4 fl. oz (118 mL)

NURTURE BARRIER

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59973-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMMONIUM ACRYLOYLDIMETHYLTaurate/VP COPOLYMER (UNII: W59H9296ZG)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ORANGE OIL (UNII: AKN3KSD11B)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
MANDARIN OIL (UNII: NJO720F72R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCINE (UNII: TE7660XO1C)	
PROLINE (UNII: 9DLQ4CIU6V)	
TAURINE (UNII: 1EQV5MLY3D)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ACETYLCYSTEINE (UNII: WYQ7N0BPYC)	
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
VANILLIN (UNII: CHI530446X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59973-001-01	118 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/01/2012	

Establishment			
Name	Address	ID/FEI	Business Operations
Omega Packaging		36 128 199 1	manufacture(59973-001)

Revised: 8/2013

Rise Global Products