

SKIN RELIEF OATMEAL DAILY MOISTURIZING- 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.

Daily Moisturizing Lotion Oatmeal 8 oz

Active Ingredient Purpose

Dimethicone 1/3% Skin Protectant

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 condition 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.

DISTRIBUTED BY:

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

MADE IN CHINA

Inactive Ingredients water, petrolatum, isopropyl myristate, glycerin, glyceryl stearate, propylene glycol, PEG-100 stearate, polyacrylamide, cetyl alcohol, avena sativa (oat) kernel extract, fragrance, DMDM hydantoin, stearyl alcohol, c13-14 isoparaffin, laureth-7, disodium EDTA, methylparaben, propylparaben.



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.	
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.	

144790 1812
 DISTRIBUTED BY
 GREENBRIER INTERNATIONAL, INC.
 500 VOLVO PARKWAY,
 CHESAPEAKE, VA 23320
 MADE IN CHINA

6 39277 49931 8

SKIN RELIEF OATMEAL DAILY MOISTURIZING

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
WATER (UNII: 059QF0K00R)	
MINERAL OIL (UNII: T5L8T28FGP)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C00X)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OAT (UNII: Z6J799EAJK)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-114-01	227 g in 1 TUBE; Type 0: Not a Combination Product	12/16/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	12/16/2018		

Labeler - China Ningbo Shangge Cosmetic Technology Corp (529287434)

Establishment				
Name	Address	ID/FEI	Business Operations	
China Ningbo Shangge Cosmetic Technology Corp		529287434	manufacture(58503-114)	

Revised: 12/2018

China Ningbo Shangge Cosmetic Technology Corp