# OATMEAL - dimethicone lotion GREENBRIER INTERNATIONAL

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.

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#### **Drug Facts**

Active Ingredient Purpose

Dimethicone 0.15% Skin Protectant

Help prevent and temporarily protects chafed, chapped or cracked skin. Helps prevent and protect from the drying effects of wind and cold weather.

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

Apply as needed, and do not get into eyes.

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.

apply as needed

water, mineral oil, cetyl alcohol, glycerin, propylene glycol, methylparaben, propylparaben, DMDM hydantoin, steareth-30, ammonium polyacrylate, C13-16 isoparaffin, glyceryl stearate, fragrance, avena sativa (oat) protein extract



### **OATMEAL**

dimethicone lotion

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:33992-1129

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

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	Ingredient Name	Basis of Strength	Strength
	dimethicone (UNII: 92RU3N3Y1O) (dimethicone - UNII:92RU3N3Y1O)	dimethicone	0.15 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
mineral oil (UNII: T5L8T28FGP)		
cetyl alcohol (UNII: 936JST6JCN)		
petrolatum (UNII: 4T6H12BN9U)		
glycerin (UNII: PDC6A3C0OX)		
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)		
dmdm hydantoin (UNII: BYR0546TOW)		
propylparaben (UNII: Z8IX2SC1OH)		
methylparaben (UNII: A218 C7H19 T)		
steareth-30 (UNII: 5776GCL1DG)		

]	Packaging				
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:33992-1129-1	340.2 g in 1 BOTTLE, PLASTIC			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	12/06/2011		

## Labeler - GREENBRIER INTERNATIONAL (610322518)

## **Registrant - NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD. (529047265)**

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD.		529047265	manufacture