

XTRACARE 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.

XtraCare Skin Relief Oatmeal Daily Moisturizing

□Active Ingredient Purpose

Dimethicone 1/3% Skin Protectant

XtraCare Skin Relief Oatmeal Daily Moisturizing Lotion

dimethicone skin protectant

with soothing oat essence

To Protect & Relieve Dry Skin

12 fl oz (354 mL)

□Keep out of reach of children. □ If swallowed, get medical help or contact a Poison Control Center right away.

□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.

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:

REJOICE INTERNATIONAL INC.

48325 BINGHAMPTON DR.,

NORTHVILLE, MI 48168 USA

MADE IN CHINA

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

XtraCare[®]

Skin Relief
Oatmeal

Daily Moisturizing Lotion

dimethicone skin protectant



with soothing
oat essence

To Protect &
Relieve Dry Skin

12 FL OZ (354mL)

Drug Facts

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Other information Store at room temperature.

Inactive ingredients Water, Paraffinum Liquidum, Isopropyl Myristate, Glycerin, Glyceryl Stearate, Propylene Glycol, PEG-100 Stearate, Polyacrylamide, Cetyl Alcohol, Avena Sativa Kernel Extract, Fragrance, DMDM Hydantoin, Stearyl Alcohol, C13-14 Isoparaffin, Laureth-7, Disodium EDTA, Methylparaben, Propylparaben.



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skin relief
Oatmeal

Daily Moisturizing Lotion
dimethicone skin protectant



with soothing
oat essence

to protect &
relieve dry skin

fragrance free

NET WT 8 OZ (227g)

skin relief
Oatmeal
Daily Moisturizing Lotion

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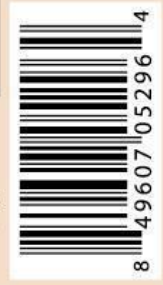
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Questions/Comments? 1-855-345-5575

Inactive ingredients Water, Petrolatum, Mineral Oil, Glycerin, Glyceryl Stearate, Propylene Glycol, PEG-100 Stearate, Polyacrylamide, Cetyl Alcohol, Avena Sativa (Oatmeal) Kernel Extract, Fragrance, DMDM Hydantoin, Stearyl Alcohol, C13-14 Isoparaffin, Laureth-7, Disodium EDTA, Methylparaben, Propylparaben.



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XTRACARE SKIN RELIEF OATMEAL DAILY MOISTURIZING
dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-037	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	5 mg in 354 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)			
	MINERAL OIL (UNII: T5L8T28FGP)			
	ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)			
	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)			
	METHYLPARABEN (UNII: A2I8C7HI9T)			
	PROPYLPARABEN (UNII: Z8IX2SC1OH)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-037-01	354 mg in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2013	
2	NDC:58503-037-02	227 mg in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2013	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	11/26/2013		

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

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp		529287434	manufacture(58503-037)

