

**XTRACARE WITH COOLING ACTION OATMEAL SKIN RELIEF CALMIN-
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 with cooling action Oatmeal Skin Relief Calmin

Active Ingredient Purpose

Dimethicone 1/3% Skin Protectant

XtraCare (with cooling action) Oatmeal Skin Relief Calming Lotion

dimethicone skin protectant

with natural colloidal oatmeal

provides immediate and lasting moisture relief for itchy, extra dry skin

12 fl oz (354 mL)

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.

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, menthol, aloe barbadensis leaf juice, methylparaben, propylparaben.

XtraCare[®]

with cooling action

Oatmeal

**Skin Relief
Calming Lotion**

dimethicone skin protectant



with natural
colloidal oatmeal

provides immediate
and lasting moisture
relief for itchy, extra dry skin

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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, Menthol, Aloe Barbadosis Leaf Juice, Methylparaben, Propylparaben.



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with cooling action
Oatmeal

**Skin Relief
Calming Lotion**
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NET WT 8 OZ (227g)

with cooling action
Oatmeal
Skin Relief Calming Lotion

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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, Menthol, Aloe Barbadensis Leaf Juice, Methylparaben, Propylparaben.



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-038	
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)				
MENTHOL (UNII: L7T10EIP3A)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
METHYL PARABEN (UNII: A218C7HI9T)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-038-01	354 mg in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2013	
2	NDC:58503-038-02	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
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Revised: 9/2019

China Ningbo Shangge Cosmetic Technology Corp.