

**XTRACARE WITH COOLING ACTION OATMEAL SKIN RELIEF CALMIN-
dimethicone lotion
Rejoice International**

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.

label

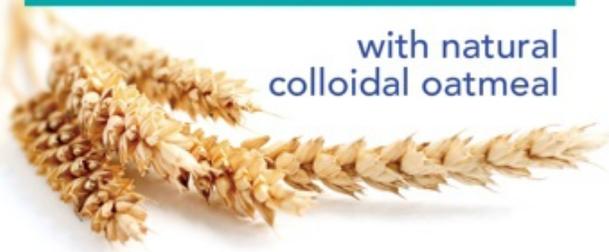


with cooling action

Oatmeal

**Skin Relief
Calming Lotion**

dimethicone skin protectant



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Drug Facts

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Inactive ingredients Water, Petrolatum, Cetearyl Alcohol, Polyacrylamide, Glyceryl Stearate, PEG-100 Stearate, Glycerin, Propylene Glycol, Phenoxyethanol, C13-14 Isoparaffin, Methylparaben, Fragrance, Laureth-7, Disodium EDTA, Isopropyl Myristate, Avena Sativa (Oat) Kernel Extract, Menthol.

Questions/comments? 1-855-345-5575



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REJOICE INTERNATIONAL CORP.
NORTHVILLE, MI 48167, USA
MADE IN CHINA

XTRACARE WITH COOLING ACTION OATMEAL SKIN RELIEF CALMIN

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-038
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
MINERAL OIL (UNII: T5L8T28FGP)	

ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PEG-100 STEARATE (UNII: YD01N1999R)
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWW)
CETYL ALCOHOL (UNII: 936JST6JCN)
OAT (UNII: Z6J799EAJK)
DMDM HYDANTOIN (UNII: BYR0546TOW)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
LAURETH-7 (UNII: Z95S6G8201)
EDETATE DISODIUM (UNII: 7FLD91C86K)
MENTHOL (UNII: L7T10EIP3A)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-038-01	354 mg in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2013	
2	NDC:57337-038-02	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 Drug	M016	11/26/2013	

Labeler - Rejoice International (078741245)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(57337-038)