

XTRACARE OATMEAL DAILY MOISTURIZING 8 OZ- dimethicone lotion
Rejoice International Inc.

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 Oatmeal Daily Moisturizing Lotion Tube 8 oz

Active ingredient

Dimethicone 1.3%

Purpose

Skin Protectant

Uses

- 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.

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.

Questions/comments? 1-855-345-5575



Oatmeal

Daily Moisturizing Lotion

dimethicone skin protectant

To Protect & Relieve Dry Skin



NET WT 8 OZ (227 g)

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, 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.

Questions/comments? 1-855-345-5575

333366 2104



8 49607106903 0

MANUFACTURED FOR:
REJOICE INTERNATIONAL CORP.
21800 HAGGERTY RD.
NORTHVILLE, MI 48167 U.S.A.
MADE IN CHINA

XTRACARE OATMEAL DAILY MOISTURIZING 8 OZ

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-139
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
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PETROLATUM (UNII: 4T6H12BN9U)	
OAT (UNII: Z6J799EAJK)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KOOR)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LAURETH-7 (UNII: Z95S6G8201)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-139-01	227 g in 1 TUBE; Type 0: Not a Combination Product	04/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/19/2021	

Labeler - Rejoice International Inc. (078741245)**Establishment**

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Technology Co., Ltd.		529287434	manufacture(57337-139)