

XTRACARE SKIN RELIEF OATMEAL DAILY MOISTURIZING- 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.

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:

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

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.

Daily Moisturizing Lotion

OATMEAL

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.

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 (Oatmeal) Kernel Extract, DMDM Hydantoin, Stearyl Alcohol, C13-14 Isoparaffin, Laureth-7, Disodium EDTA, Methylparaben, Propylparaben.

196593 - 14454 - 001-1405

DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320
MADE IN CHINA



6 39277 96593 6

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0054
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: 2KR89I4H1Y)	
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:33992-0054-2	354 mg in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2014	
2	NDC:33992-0054-1	227 mg in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/19/2014	

Labeler - Greenbrier International (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp		529 287434	manufacture(33992-0054)

Revised: 4/2019

Greenbrier International