

BABY XTRACARE OATMEAL- 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.

Baby XtraCare Oatmeal

Active Ingredient

Purpose

Dimethicone 1.2% Skin Protectant

Use

Help prevent and temporarily protects chafed, chapped, or cracked skin.

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

Baby XtraCare®

Oatmeal Daily Moisturizing Lotion

Lightly Scented

Dimethicon Skin Protectant with Natural Oat Extract

Helps Soothe & Soften Baby's Skin

12 FL OZ (354 mL)

Directions

Apply liberally as often as needed.

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.

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, aloe barbadensis leaf juice, methylparaben, propylparaben.

Other Information Store at room temperature.

Questions/Comments? 1-855-345-5575

DISTRIBUTED BY

REJOICE INTERNATIONAL INC

NORTHVILLE, MI 48168 U.S.A.

MADE IN CHINA



Oatmeal Daily Moisturizing Lotion

LIGHTLY SCENTED

Dimethicone Skin Protectant with Natural Oat Extract



Helps Soothe & Protect Baby's Skin

NET WT 8 OZ (227 g)



Oatmeal Daily Moisturizing Lotion

Drug Facts

Active Ingredient	Purpose
Dimethicone 1.2%.....	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.

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, Aloe Barbadensis Leaf Juice, Methylparaben, Propylparaben.

DISTRIBUTED BY:
REJOICE INTERNATIONAL INC.
NORTHVILLE, MI 48168, USA
MADE IN CHINA





Oatmeal Daily Moisturizing Lotion

LIGHTLY SCENTED
Dimethicone Skin Protectant
with Natural Oat Extract



Helps Soothe & Soften Baby's Skin
12 FL OZ (354 mL)

Drug Facts

Active Ingredient Purpose
Dimethicone 1.2% 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.

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, Aloe Barbadensis Leaf Juice, Methylparaben, Propylparaben.



8 49607 05834 8

QUESTIONS/COMMENTS?
1-855-345-5575

DISTRIBUTED BY
REJOICE INTERNATIONAL, INC
NORTHVILLE, MI 48168 U.S.A.
MADE IN CHINA

BABY XTRACARE OATMEAL

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-070-01	227 g in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2015	
2	NDC:58503-070-02	354 g in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/16/2015	

Labeler - China Ningbo Shangge Cosmetic Technology Corp (529287434)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp		529287434	manufacture(58503-070)

Revised: 9/2019

China Ningbo Shangge Cosmetic Technology Corp