

CETAPHIL CRACKED SKIN REPAIR- dimethicone lotion
Galderma Laboratories, L.P.

Drug Facts

Active ingredients.....Purpose

Dimethicone 2%.....Skin protectant

Uses

- helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin
- temporary protects minor:
 - cuts ● scrapes ● burns
- helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only.

When using this product ● do not get into eyes.

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.

Do not use on ● deep or puncture wounds ● animal bites ● serious burns

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

Directions

- Apply generously to affected area as needed

Inactive Ingredients

CAPRYLIC/CAPRIC TRIGLYCERIDE, HYDROGENATED CASTOR OIL, LACTIC ACID, METHOXY PEG-22/DODECYL GLYCOL COPOLYMER, METHYLPARABEN, MINERAL OIL, OZOKERITE, PEG-2 HYDROGENATED CASTOR OIL, PEG-7 HYDROGENATED CASTOR OIL, PROPYLPARABEN, SODIUM LACTATE, SORBITAN ISOSTEARATE, UREA, WATER

Questions or comments?

1-866-735-4137

Distributed By:

Galderma Laboratories, L.P.
Dallas, TX 75201

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Made in Canada

cetaphil.com

PRINCIPLE DISPLAY PANEL - 16 FL OZ pump label

Dermatologist Recommended
For Sensitive Skin

Cetaphil®

Cracked Skin Repair Lotion

Skin Protectant Dimethicone

Rough, Cracked Sensitive Skin

Daily use lotion is designed to hydrate
and restore rough skin and prevent
cracked skin from coming back.

Urea

5 skin sensitivity signs

16 FL OZ (473 mL)

P56383-1

DERMATOLOGIST RECOMMENDED
FOR SENSITIVE SKIN



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Skin Protectant Dimethicone

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Daily use lotion is designed to hydrate and restore rough skin and prevent cracked skin from coming back.

Urea



P56383-1

16 FL OZ (473 mL)

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0299-4114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Hydrogenated Castor Oil (UNII: ZF94AP8MEY)	
Lactic Acid, Unspecified Form (UNII: 33X04XA5AT)	
Methoxy Peg-22/Dodecyl Glycol Copolymer (UNII: 2T6YOF5WQT)	
Methylparaben (UNII: A2I8C7HI9T)	
Mineral Oil (UNII: T5L8T28FGP)	
Ceresin (UNII: Q1LS2UJO3A)	
Peg-7 Hydrogenated Castor Oil (UNII: WE09129TH5)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sodium Lactate (UNII: TU7HW0W0QT)	
Sorbitan Isostearate (UNII: 01S2G2C1E4)	
Urea (UNII: 8W8T17847W)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4114-00	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	05/01/2021	

Labeler - Galderma Laboratories, L.P. (047350186)

Establishment

Name	Address	ID/FEI	Business Operations
G Production Inc.		251676961	manufacture(0299-4114)

