

MEDLINE- dimethicone cream
Medline Industries, LP

159 Remedy Specialized Silicone Cream

Active ingredient

Dimethicone 12.5% w/v

Purpose

Skin protectant

Uses

- helps treat and prevent diaper rash
- protects minor skin irritation with diaper rash and helps seal out wetness

Warnings

For external use only

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last for 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 right away.

Directions

- change wet and soiled diapers promptly, cleans the diaper area and allow to dry
- apply cream liberally as often as necessary with each diaper change especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information

- protect from freezing, avoid excessive heat

Inactive ingredients

7-dehydrocholesterol, aphanizomenon flos-aquae (algae) extract, bisabolol, brassica campestris (rapeseed) sterols, camellia sinensis (green tea) leaf extract, caprylic/capric triglycerides, carthamus tinctorius (safflower) oleosomes, cetylhydroxyproline palmitamide, cholecalciferol, dimethicone crosspolymer, dimethiconol, divinyl dimethicone/dimethicone copolymer emulsion, eugenia caryophyllus (clove) flower extract, glycerin, hexyldecanol, hydrolyzed soy protein, jojoba esters, lauryl PEG-10 tris (trimethylsiloxy) silylethyl dimethicone, manuka honey, olea europaea (olive) oil, PEG/PPG-18/18 dimethicone, phenoxyethanol, phospholipids, phytonadione, propanediol, purified water, sodium chloride, stearic acid, tocopheryl acetate, yeast ferment extract, zea mays (corn) oil.

Manufacturing Information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA of domestic and imported materials

www.medline.com

1-800-MEDLINE (633-5463)

REF: MSC092564

V3 RJ23BLB

Package Label

NDC 53329-159-04



SPECIALIZED

PREVENT

Silicone Cream

For providing a breathable moisture film



CHG Compatible
Paraben Free
Hypoallergenic
Pediatrician Tested

Unscented

4 FL OZ (118 mL)



Drug Facts

Active ingredient Dimethicone 12.5% w/v **Purpose** Skin Protectant

Uses
■ Helps treat and prevent diaper rash ■ Protects minor skin irritation associated with diaper rash and helps seal out wetness

Warnings
For external use only

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

When using this product ■ do not get into eyes

Stop use and ask a doctor if ■ condition worsens ■ symptoms last for 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 right away.

Directions ■ change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry ■ apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information Protect from freezing. Avoid excessive heat.

Inactive ingredients 7-dehydrocholesterol, aphanizomenon flos-aquae (algae) extract, bisabolol, brassica campestris (rapeseed) sterols, camellia sinensis (green tea) leaf extract, caprylic/capric triglycerides, carthamus tinctorius (safflower) oleosomes, cetylhydroxyproline palmitamide, cholecalciferol, dimethicone crosspolymer, dimethiconol, divinyl dimethicone/dimethicone copolymer emulsion, eugenia caryophyllus (clove) flower extract, glycerin, hexyldecanol, hydrolyzed soy protein, jojoba esters, lauryl PEG-10 tris (trimethylsiloxy) silylethyl dimethicone, manuka honey, olea europaea (olive) oil, PEG/PPG-18/18 dimethicone, phenoxyethanol, phospholipids, phytonadione, propanediol, purified water, sodium chloride, stearic acid, tocopheryl acetate, yeast ferment extract, zea mays (corn) oil.



REF MSC092564

www.medline.com ©2022 Medline and Medline Remedy are registered trademarks of Medline Industries, LP. Made in USA of domestic and imported materials. Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA. 1-800-MEDLINE V3 RJ23BLB

MEDLINE

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CLOVE (UNII: K48IKT5321)	
HEXYLDECANOL (UNII: 151Z7P1317)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
APHANIZOMENON FLOSAQUAE (UNII: 49VG1X560X)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HONEY (UNII: Y9H1V576FH)	
CETYLHYDROXYPROLINE PALMITAMIDE (UNII: 74ONU0S62G)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
PHYTONADIONE (UNII: A034SE7857)	
PROPANEDIOL (UNII: 5965N8W85T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CORN OIL (UNII: 8470G57WFM)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
LEVOMENOL (UNII: 24WE03BX2T)	
RAPESEED STEROL (UNII: B46B6DD20U)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
7-DEHYDROCHOLESTEROL (UNII: BK1IU07GKF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-159-13	59 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2023	
2	NDC:53329-159-04	118 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2023	
3	NDC:53329-159-77	4 mL in 1 PACKET; Type 0: Not a Combination Product	05/01/2024	
4	NDC:53329-159-96	144 in 1 BOX	05/01/2024	
4		4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	04/01/2023	

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 5/2024

Medline Industries, LP