

**DR BUTLER DIAPER RASH- dimethicone 1% cream
Beyond Health P.A.**

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.

Dr. Butler Diaper Rash Cream

Dimethicone 1%

Skin Protectant

Helps treat and prevent diaper rash, protects minor skin irritation due to diaper rash and helps seal out wetness.

For external use only.

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

When using this product avoid contact with 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.

If swallowed, seek medical help or contact a Poison Control Center immediately.

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.

Water, glycerin, petrolatum, panthenol, stearyl alcohol, steareth-20, isopropyl palmitate, cetyl alcohol, avena sativa (oat) kernel oil, sodium hyaluronate, hamamelis virginiana (witch hazel) leaf extract, rosmarinus officinalis (rosemary) leaf extract, claudia officinalis flower extract, chamomilla recutita (matricaria) flower extract, curcuma longa (turmeric) root extract, olea europaea (olive) leaf extract, lavandula angustifolia (lavender) flower extract, helichrysum italicum extract, centella asiatica extract, panax ginseng root extract, aesculus hippocastanum (horse chestnut) extract, melaleuca alternifolia (tea tree) leaf extract, carya ovata bark extract, avena sativa (oat) kernel extract, cucumis sativus (cucumber) fruit extract, sorbitol, lecithin, xanthan gum, oleic acid, iron oxides (CI 77491), phenoxyethanol, ethylhexylglycerin, sodium chloride, colloidal oatmeal, 4-t-butylcyclohexanol, pentylene glycol, benzalkonium chloride, ceramide NP.

Drug Facts

Active ingredient	Purpose
Dimethicone 1%	Skin protectant

Uses • helps treat and prevent diaper rash
 • protects minor skin irritation due to diaper rash and helps seal out wetness

Warnings
 For external use only

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

When using this product • avoid contact with 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

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

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 • store between 15°-30°C (59°-86°F)

Inactive ingredients water, glycerin, petrolatum, panthenol, stearyl alcohol, steareth-20, isopropyl palmitate, cetyl alcohol, avena sativa (oat) kernel oil, sodium hyaluronate, hamamelis virginiana (witch hazel) leaf extract, rosmarinus officinalis (rosemary) leaf extract, calendula officinalis flower extract, chamomilla recutita (matricaria) flower extract, curcuma longa (turmeric) root extract, olea europaea (olive) leaf extract, lavandula angustifolia (lavender) flower extract, helichrysum italicum extract, centella asiatica extract, panax ginseng root extract, aesculus hippocastanum (horse chestnut) extract, melaleuca alternifolia (tea tree) leaf extract, carya ovata bark extract, avena sativa (oat) kernel extract, cucumis sativus (cucumber) fruit extract, sorbitol, lecithin, xanthan gum, oleic acid, iron oxides (CI 77491), phenoxyethanol, ethylhexylglycerin, sodium chloride, colloidal oatmeal, 4-t-butylcyclohexanol, pentylene glycol, benzalkonium chloride, ceramide NP

www.DoctorButlers.com



Diaper Rash Cream
New

Made in the U.S.A. with Domestic and Foreign Components.

Cruelty Free - No Animal Testing

Questions? Contact us via our website

Distributed by:
Beyond Health P.A. • Tequesta, FL 33469
Phone: (561) 935-9698

PROTECTIVE & COMFORTING FORMULA
Hypoallergenic

- Fragrance Free
- Helps Reduce Redness
- Calms Burning & Irritation in Chafed Skin
- Contains a Blend of Natural Herbal Extracts

PROCTOLOGIST DEVELOPED

DIAPER RASH CREAM

Protection & Relief From Diaper Rash & Skin Irritation

NET WT 3 OZ (85g)



"Leave the Pain Behind"®

Proctologist Developed
Protection & Comfort Cream

PROTECTIVE & COMFORTING FORMULA



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DR BUTLER DIAPER RASH

dimethicone 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70942-259
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE 350 (UNII: 2Y53S6ATLU) (DIMETHICONE 350 - UNII:2Y53S6ATLU)	DIMETHICONE 350	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
SORBITOL (UNII: 506T60A25R)	
CARYA OVATA BARK (UNII: X765CF609L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OATMEAL (UNII: 8PI54V663Y)	
CUCUMBER (UNII: YY7C30VXJT)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WW9CM0O67Z)	
4-TERT-BUTYLCYCLOHEXANOL (UNII: K0H1405S9C)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
CHAMOMILE (UNII: FGL3685T2X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
STEARETH-20 (UNII: L0Q8IK9E08)	
WATER (UNII: 059QF0KO0R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
ROSEMARY (UNII: IJ67X351P9)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (C12-C16) (UNII: F5UM2KM3W7)	
CERAMIDE NP (UNII: 4370DF050B)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
HELICHRYSUM ITALICUM FLOWER (UNII: P62Y550X24)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
OLEIC ACID (UNII: 2UMI9U37CP)	
TURMERIC (UNII: 856YO1Z64F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70942-259-03	85 g in 1 CAN; Type 0: Not a Combination Product	03/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	03/22/2023	

Labeler - Beyond Health P.A. (026781064)

Registrant - Derma Care Research Labs (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(70942-259)

Revised: 3/2023

Beyond Health P.A.