

DR. MOM BUTT BALM- dimethicone petrolatum ointment
Ferndale Laboratories, Inc.

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. Mom Butt Balm

Active Ingredients

Dimethicone 28%

Petrolatum 48%

Purpose

Dimethicone 28%.....Skin protectant

Petrolatum 48%.....Skin protectant

Uses

- helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin

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 as needed

Other information

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

Inactive Ingredients

aluminum starch octenylsuccinate, fractionated coconut oil, magnesium hydroxide, spearmint oil

Questions?

Toll free (888) 548-0900

Package Display



Dr. Mom Butt Balm® was created by a physician when nothing on the store shelves relieved her baby's painful diaper rash. The formula was perfected with dermatologists to ensure it is safe and soothing for delicate baby skin - a better solution to help parents deal with diaper rash to keep their baby's skin healthy and happy.

butt balm



Helps prevent and treat diaper rash

Dimethicone and Petrolatum
Skin Protectant

Free of artificial dyes and preservatives

NET WT. 2.5 oz (70 g)

Distributed by
FERNDALE
HEALTHCARE, INC.
Ferndale, MI 48220 U.S.A.
Toll free (888) 548-0900

Manufactured by
Ferndale Laboratories, Inc.
Ferndale, MI 48220

Rev.: 04/21



Mind of a doctor, heart of a mom™

butt balm®



Created with loving care for your baby.

Drug Facts	
Active Ingredients	Purpose
Dimethicone 28%	Skin protectant
Petrolatum 48%	Skin protectant
Uses ■ helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin	
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 as needed	
Other information	
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].	
Inactive Ingredients	
aluminum starch octenylsuccinate, fractionated coconut oil, magnesium hydroxide, spearmint oil	
Questions? Toll free (888) 548-0900	



Helps protect and soothe baby's skin from wetness, acidity and chafing.

Refreshing, natural scent.

Designed with dermatologists.

Easy to apply and clean from baby's skin with no messy white residue.

Hypoallergenic

DR. MOM BUTT BALM
dimethicone petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0496-0590
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.28 g in 1 g
WHITE PETROLATUM (UNII: B6E5W8RQJ4) (WHITE PETROLATUM - UNII:B6E5W8RQJ4)	WHITE PETROLATUM	0.48 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SPEARMINT OIL (UNII: C3M81465G5)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0496-0590-02	70 g in 1 TUBE; Type 0: Not a Combination Product	11/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	11/07/2022	

Labeler - Ferndale Laboratories, Inc. (005320536)**Establishment**

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0590)

Revised: 10/2022

Ferndale Laboratories, Inc.