

**TENA BARRIER CREAM- dimethicone cream**  
**Essity HMS North America 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.*

-----  
**Active Ingredient**

Dimethicone 1.2%

**Purpose**

Skin Protectant

**Uses**

- protects skin from irritation caused by contact with urine and/or stool
- helps prevent and relieve chafed, chapped or cracked skin

**Warnings**

**For external use only.**

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

**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

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

**Directions**

- cleanse skin with TENA® Cleansing Cream and/or TENA® Washcloths
- apply cream liberally and reapply as needed

**Other Information** Store between 32°F and 85°F

**Inactive Ingredients:** Acacia Decurrens

Flower Wax, Allantoin, Aloe Barbadosis Leaf Juice, Avena Sativa (Oat) Kernel Flour, Behentrimonium Methosulfate, Butylene Glycol, Calendula Officinalis Flower Oil, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Copernicia Cerifera (Carnauba) Wax, Distearyldimonium Chloride, Ethylhexylglycerin, Glycerin, Helianthus Annus (Sunflower) Seed Wax, Hydrogenated Castor Oil, Isopropyl Palmitate, Jojoba Esters, Lactic Acid, Phenoxyethanol, Polyglycerin-3, Potassium Sorbate, Ricinus Communis (Castor) Seed Oil,

Sodium Benzoate, Sodium Chloride, Sorbitan Caprylate, Water

**Questions or comments?**

Call 1-800-992-9939 or visit [www.tena.us](http://www.tena.us)



Barrier Cream

Delicate &  
fragile skin



Scent free

Dimethicone

3.4 fl oz  
100 ml

Barrier Cream

<b>Drug Facts</b>		<b>Drug Facts (Continued)</b>	
<b>Active Ingredient</b>	<b>Purpose</b>	<b>Other Information</b>	Store between 32°F and 85°F
Dimethicone 1.2%	Skin Protectant	<b>Inactive Ingredients:</b>	Acacia, Docurans Flower Wax, Allantoin, Aloe Barbadosis, Lact Juice, Avena Sativa (Oat) Kernel Flour, Behentrimonium Methosulfate, Butylene Glycol, Calendula Officinalis Flower Oil, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Copernicia Cerifera (Carnauba) Wax, Distearyl-dimonium Chloride, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Wax, Hydrogenated Castor Oil, Isopropyl Palmitate, Jojoba Esters, Lactic Acid, Phenylethanol, Polyglycerin-3, Potassium Sorbate, Ricinus Communis (Castor) Seed Oil, Sodium Benzoate, Sodium Chloride, Sorbitan Caprylate, Water
<b>Uses</b>		<b>Questions or comments?</b>	
<ul style="list-style-type: none"> <li>• protects skin from irritation caused by contact with urine and/or stool</li> <li>• helps prevent and relieve chafed, chapped, or cracked skin</li> </ul>		Call 1-800-992-9939 or visit <a href="http://www.tena.us">www.tena.us</a>	
<b>Warnings</b>		<b>Directions</b>	
<p><b>For external use only.</b></p> <ul style="list-style-type: none"> <li><b>Do not use</b> on deep or puncture wounds</li> <li>on animal bites</li> <li>on serious burns</li> </ul> <p><b>When using this product</b> do not get into eyes</p> <p><b>Stop use and ask a doctor if</b> condition worsens</p> <ul style="list-style-type: none"> <li>• symptoms last more than 7 days or clear up and occur again within a few days</li> </ul> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</p>		<ul style="list-style-type: none"> <li>• cleanse skin with TENA® Cleansing Cream and/or TENA® Washcloths</li> <li>• apply cream liberally and reapply as needed</li> </ul>	
<b>Directions</b>		<b>Not made with natural rubber latex.</b>	

64409



7 68702 64409 9

Room No. \_\_\_\_\_ Name \_\_\_\_\_



**Manufactured for:**  
Essity HMS North America Inc.  
7030 Louisville Road, Bowling Green, KY 42101

**Distributed by:**  
Essity HMS North America Inc.  
999 Farrell, Drummondville, Québec J2C 5P6



# TENA BARRIER CREAM

dimethicone cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59608-005
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	.012 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
BEHENTRIMONIUM METHO SULFATE (UNII: 5SHP745C61)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MATRICARIA CHAMOMILLA LEAF (UNII: 6I9LN466F0)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
LACTIC ACID (UNII: 33X04XA5AT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CASTOR OIL (UNII: D5340Y2I9G)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITAN MONOCAPRYLATE (UNII: 1VTA8DCP5Q)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59608-005-17	100 mL in 1 TUBE; Type 0: Not a Combination Product	07/29/2018	

2	NDC:59608-005-34	5 mL in 1 BAG; Type 0: Not a Combination Product	07/29/2018	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347		07/29/2018	

**Labeler** - Essity HMS North America Inc (787850148)

Revised: 9/2018

Essity HMS North America Inc