AVEENO - dimethicone lotion Physicians Total Care, 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.

Aveeno_® Active Naturals™ Daily Moisturizing LOTION

Drug Facts

Active ingredient

Dimethicone 1.25%

Purposes

Skin Protectant

Uses

• Helps prevent and temporarily protects 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.

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

Directions

• Apply liberally as often as needed.

Inactive ingredients

Avena Sativa (Oat) Kernel flour, Benzyl Alcohol, Cetyl Alcohol, Distearyldimonium Chloride, Glycerin, Isopropyl Palmitate, Petrolatum, Sodium Chloride, Water

Questions?

1-877-288-2525 or visit www.Aveeno.com

PRINCIPAL DISPLAY PANEL

dermatologist recommended

 $\begin{array}{l} Aveeno_{\Re} \\ ACTIVE NATURALS_{\Re} \end{array}$

Daily Moisturizing LOTION **dimethicone skin protectant**

clinically proven to relieve dry skin

moisturizes for 24 hours fragrance free

with natural colloidal oatmeal

18 fl. oz. (532 mL)

NDC 54868-5875-0



Additional barcode labeling by: Physicians Total Care, Inc. Tulsa, Oklahoma 74146

AVEENO dimethicone lotion								
Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5875(NDC:5	8232-9907)				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name			Basis of Strength	Strength				
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)			Dimethicone	13 mg in 1 g				

Inactive Ingredients							
Ingredient Name					Strength		
AVENA SATIVA FLOWE							
Benzyl Alcohol (UNII: LF							
Cetyl Alcohol (UNII: 936	JST6JCN)						
Distearyldimonium Chle	oride (UNII: OM9573ZX3X)						
Glycerin (UNII: PDC6A30							
Isopropyl Palmitate (UNII: 8 CRQ 2 TH6 3 M)							
Petrolatum (UNII: 4T6H1	Petrolatum (UNII: 4T6H12BN9U)						
Sodium Chloride (UNII:	Sodium Chloride (UNII: 451W47IQ8X)						
Water (UNII: 059QF0KO	0 R)						
Packaging							
# Item Code	Package Description	Marketing Start Date		Ma	Marketing End Date		
1 NDC:54868-5875-0	532 g in 1 BOTTLE, PUMP						
Marketing Information							
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date		
OTC monograph final	part347		03/31/2008				

Labeler - Physicians Total Care, Inc. (194123980)

Establishment				
Name	Address	ID/FEI		Business Operations
Physicians Total Care, Inc.		194123980	relabel	

Revised: 5/2012

Physicians Total Care, Inc.