

AVANCE CURE BARRIER- allantoin, dimethicone, menthol cream
SMART CHOICE MEDICAL 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:

- ALLANTOIN 0.5%
- DIMETHICONE 2%
- MENTHOL 0.45%

PURPOSE:

SKIN PROTECTANT

SKIN PROTECTANT

TOPICAL ANALGESIC

USES

- HELPS TREAT AND PREVENT DIAPER RASH. PROTECTS CHAFED SKIN/MINOR SKIN IRRITATION DUE TO/ASSOCIATED WITH DIAPER RASH
- HELPS PROTECTS FROM/SEAL OUT WETNESS
- TEMPORARLY PROTECTS AND HELPS RELEIVE CHAFED, CHAPPED, OR CRACKED SKIN

WARNINGS:

- FOR EXTERNAL ONLY

DO NOT USE:

- ON DEEP PUNCTURE WOUNDS
- ON INFECTIONS
- ON LACERATIONS

WHEN USING THIS PRODUCT:

- AVOID CONTACT WITH EYES

STOP USE AND ASK A DOCTOR IF:

- CONDITION WORSENS OR DOES NOT IMPROVE WITHIN 7 DAYS

KEEP OUT OF REACH OF CHILDREN:

- IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY

DIRECTIONS:

GENTLY CLEAN THE IRRITATED AREA BEFORE USE. THEN APPLY A GENEROUS LAYER OF CREAM.

IT CAN BE LEFT ON THICK OR RUBBED INTO SKIN. USE AS MANY TIMES A DAY AS NECESSARY

UNTIL HEALED. FOR CONTINUOUS PROTECTION AND HEALTHY SKIN USE DAILY.

INACTIVE INGREDIENTS:


ALOE BARBADENSIS (ALOE VERA) LEAF JUICE, BUTYROSPERMUM PARKII (SHEA BUTTER), GLYCERIN,

BEESWAX, CETEARYL ALCOHOL, CARTHAMUS TINDORIUS (SAFFLOWER) SEED OIL, POLYSORBATE 60,

MAGNESIUM ALUMINUM SILICATE, CALAMINE, ZINC PCA, AVENA SATIVA (OAT) KERNEL FLOUR, SODIUM PCA,

PANTHENOL (VITAMIN B5), TOCOPHERYL ACETATE (VITAMIN E), SODIUM HYALURONATE, GLYCERYL STEARATE,

SOBIC ACID, SODIUM PHYTATE, XANTHAN GUM, PHENOXYETHANOL, ETHYHEXYLGLYCERIN



with **TRIDERMA** MLD





Avancé Cure Barrier

Healing Barrier Cream


Medical-Strength Formula With Botanicals, Menthol & Calamine
 Helps Protect and Heal:
 Incontinence, Stubborn Diaper Rash, Chafed/Cracked Skin

This non greasy cream is unlike traditional barrier or incontinence creams that use Zinc Oxide to form a white sticky barrier. Instead, this concentrated formula uses key ingredients to provide non-sticky wetness protection and provide soothing relief and even faster healing for the most severe and hard-to-heat rashes.







Aloe Vera




Beeswax



Shea Butter



Oat Proteins



Vitamins B & E

Drug Facts

Active Ingredient	Purpose	Directions
Azelaic Acid 15%	Skin protectant	Apply to the affected area before use. Then apply a generous layer of cream. It may be left on skin or rinsed with water. Use as many times a day as necessary until healed. For continuous protection and healthy skin, use daily.
Hydrocortisone 2.5%	Skin protectant	
Menthol 0.40%	Topical Anesthetic	
Warnings		
Do not use in deep puncture wounds in on infections in on lacerations		
When using this product in brief contact with eyes		
Stop use and ask a doctor if in condition worsens or does not improve within 7 days		
Keep out of reach of children. If symptoms persist, get medical help or contact a Poison Control Center right away.		
Other Information		
Use in skin of most temperatures. Do not use on infants, children or adults.		
Inactive Ingredients		
aloe barbadensis (aloe vera) leaf juice, butyrospermum parkii (shea butter), glycerin, beeswax, cetearyl alcohol, cetylalumintindorius, cetylalumintindorius seed oil, polysorbate 60, magnesium aluminum silicate, calamine, zinc PCA, avena sativa (oat) kernel flour, sodium PCA, panthenol (vitamin B5), tocopheryl acetate, vitamin E, sodium hyaluronate, glyceryl stearate, sobic acid, sodium phytate, xanthan gum, phenoxyethanol, ethylhexylglycerin		
Questions? call 1-800-768-3801 or visit www.avancemedical.com		
REF: ACCMBUJ		

AVANCÉ CURE

with **TRIDERMA**
MD[®]

Avancé Cure Barrier

Healing Barrier Cream

With AP4[®]
Aloe Vera Complex

**Medical-Strength Formula
With Botanicals, Menthol
& Calamine**

Helps Protect and Heal:
Incontinence
Stubborn Diaper Rash
Chafed/Cracked Skin



Aloe Vera



Beeswax



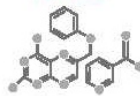
Shea Butter



Oat Proteins



**Vitamins
B & E**



Drug Facts

Active Ingredient	Purpose
Allantoin 5%	Skin protectant
Dimethicone 2%	Skin protectant
Menthol 0.45%	Topical Analgesic

Uses

- helps treat and prevent diaper rash. Protects chafed skin/minor skin irritation due to/associated with diaper rash.
- helps protect from/seal out wetness
- temporarily protects and helps relieve chafed, chapped, or cracked skin

Warnings

For external use only

Do not use

- on deep puncture wounds
- on infections
- on lacerations

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days

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

Directions

Gently clean the irritated area before use. Then apply a generous layer of cream. It can be left on thick or rubbed into skin. Use as many times a day as necessary until healed. For continuous protection and healthy skin, use daily.

Other information

- store at room temperature
- use on infants, children or adults

Inactive ingredients

aloe barbadensis (aloe vera) leaf juice, butyrospermum parkii (shea butter), glycerin, beeswax, cetearyl alcohol, carthamus tinctorius (safflower) seed oil, polysorbate 60, magnesium aluminum silicate, calamine, zinc PCA, avena sativa (oat) kernel flour, sodium PCA, panthenol (vitamin B5), tocopheryl acetate (vitamin E), sodium hyaluronate, glyceryl stearate, sorbic acid, sodium phytate, xanthan gum, phenoxyethanol, ethylhexylglycerin

Questions? call 1-800-768-3801 or visit smartchoicemedical.com

Dist. by:
Smart Choice Medical Inc.
Los Angeles, CA 90029
Made in USA
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REF: ACCMBCT



AVANCE CURE BARRIER

allantoin, dimethicone, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70936-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	.5 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.45 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
WHITE WAX (UNII: 7G1J5DA97F)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
OATMEAL (UNII: 8PI54V663Y)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SORBIC ACID (UNII: X045WJ989B)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70936-106-11	135 g in 1 TUBE; Type 0: Not a Combination Product	08/22/2016	
2	NDC:70936-106-12	270 g in 1 TUBE; Type 0: Not a Combination Product	08/22/2016	
3	NDC:70936-106-22	270 g in 1 JAR; Type 0: Not a Combination Product	08/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/22/2016	

Labeler - SMART CHOICE MEDICAL INC. (046383276)

Registrant - SMART CHOICE MEDICAL INC. (046383276)