

**TRIDERMA PROTECT AND HEAL NON- GREASY BARRIER- allantoin,
dimethicone cream**

Genuine Virgin Aloe Corporation

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.

TRIDERMA Protect & Heal Non-Greasy Barrier

Drug Facts

Active ingredients

Allantoin 1.5%

Dimethicone 2%

Purpose

Skin Protectant

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 protect 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*** •do not get into 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 or as needed.

Other information •store at room temperature •use on infants, children or adults

Inactive ingredients: water, butyrospermum parkii (shea) butter, glycerin, glyceryl stearate SE, cera alba (beeswax), cetearyl alcohol, carthamus tinctorius (safflower) seed oil, avena sativa (oat) kernel flour, aloe barbadensis leaf juice*, polysorbate 60, polysorbate 80, cetyl esters, zinc PCA, sodium PCA, panthenol (pro-vitamin B-5),

tocopheryl acetate (vitamin E), glyceryl stearate, silica, sodium hyaluronate, sodium phytate, potassium cetyl phosphate, xanthan gum, sodium hydroxide, phenoxyethanol, ethylhexylglycerin.*Certified Organic Ingredient - Mayacert Certifier

Questions? 1-800-279-7282 M-F 8am-4pm PST

Helps treat and prevent diaper rash

Temporarily protects and helps relieve chafed, chapped, or cracked skin

AP4[®] BOTANICAL

ALOE VERA COMPLEX

Allantoin & Dimethicone

Dist. by: Genuine Virgin Aloe Corp., Corona, CA 92879 Made in USA

Packaging

TRIDERMA^{MD}

Protect & Heal Non-Greasy Barrier™

Healing Cream

Helps treat and
prevent diaper rash

Temporarily protects
and helps relieve chafed,
chapped, or cracked skin



Allantoin & Dimethicone

NET WT. 4.0 OZ (113g)

Drug Facts

Active ingredients	Purpose
Allantoin 1.5%	Skin Protectant
Dimethicone 2%	Skin Protectant

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 protect 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 ■ do not get into 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.

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Questions? 1-800-279-7282 M-F 8am-4pm PST



www.triderma.com
Dist. by: Genuine Virgin Aloe Corp.,
Corona, CA 92879 © 2019
Item 61045 1019 NDC 10738-061-45



Packaging

Non Printing Area

TRIDERMA
MD

Protect & Heal Non-Greasy Barrier™

Healing Cream

Helps treat and
prevent diaper rash

Temporarily protects
and helps relieve chafed,
chapped, or cracked skin



Allantoin & Dimethicone

NET WT. 0.5 OZ (14g)

Drug Facts

Active ingredients	Purpose
Allantoin 1.5%	Skin Protectant
Dimethicone 2%	Skin Protectant

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Questions? 1-800-279-7282 M-F 8am-4pm PST

Dist. by: Genuine Virgin Aloe Corp., Corona, CA 92879
Made in USA © 2019 Item 61505 1019 NDC 10738-061-55

Non Printing Area

FRONT

BACK

Packaging

TRIDERMA MD

Protect & Heal Non-Greasy Barrier[™] Healing Cream

Drug Facts (Cont.)

polysorbate 80, cetyl esters, zinc PCA, sodium PCA, panthenol (pro-vitamin B-5), tocopheryl acetate (vitamin E), glyceryl stearate, silica, sodium hyaluronate, sodium phytate, potassium cetyl phosphate, xanthan gum, sodium hydroxide, phenoxyethanol, ethylhexylglycerin. *Certified Organic Ingredient - Mayacert Certifier

Questions? 1-800-279-7282 M-F 8am-4pm PST

crucly free MADE IN THE USA PROUDLY OWNED 12M www.triderma.com Dist. by: Genuine Virgin Aloe Corp., Corona, CA 92879 © 2019 1019



TRIDERMA MD Protect & Heal Non-Greasy Barrier[™] Healing Cream Helps treat and prevent diaper rash Temporarily protects and helps relieve chafed, chapped, or cracked skin Allantoin & Dimethicone NET WT. 0.5 OZ (14g)

Drug Facts

Active ingredients

Allantoin 1.5% Skin Protectant Dimethicone 2% Skin Protectant 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 protect and helps relieve chafed, chapped, or cracked skin

Purpose

Skin Protectant Skin Protectant Warnings For external use only. Do not use on deep puncture wounds on infections on lacerations. When using this product do not get into eyes. Stop use and ask a doctor if condition worsens or does not improve within 7 days. Keep out of reach of children.

Drug Facts (Cont.)

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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 or as needed.

Other information Store at room temperature Use on infants, children or adults

Drug Facts (Cont.)

Inactive ingredients: water, butyrospermum parkii (shea) butter, glycerin, glyceryl stearate SE, cera alba (beeswax), cetearyl alcohol, carthamus tinctorius (safflower) seed oil, avena sativa (oat) kernel flour, aloe barbadensis leaf juice, polysorbate 60,

Item 61505 NDC 10738-061-50 8 18926 01124 2

allantoin, dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10738-061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	1.5 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
OATMEAL (UNII: 8PI54V663Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
PANTHENOL (UNII: WW9CM0067Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10738-061-45	113 g in 1 TUBE; Type 0: Not a Combination Product	08/30/2019	
2	NDC:10738-061-50	1 in 1 CARTON	08/30/2019	
2	NDC:10738-061-55	14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/30/2019	

Labeler - Genuine Virgin Aloe Corporation (961374147)

Establishment

Name	Address	ID/FEI	Business Operations
Genuine Virgin Aloe Corporation		961374147	manufacture(10738-061)

Revised: 2/2023

Genuine Virgin Aloe Corporation