

TRIDERMA STUBBORN DIAPER RASH RELIEF- 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 Stubborn Diaper Rash™ Relief Cream

Drug Facts

Active ingredients

Allantoin 1.5%
Dimethicone 2.0%

Purpose

Skin Protectant

Uses •Helps treat and prevent diaper rash •Helps 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. If contact occurs, rinse thoroughly with water.

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 Change wet/soiled diapers promptly. Cleanse diaper area and allow to dry. Apply cream liberally as often as necessary with each diaper change, especially at bedtime or anytime exposure to wet diapers may be prolonged.

Other information •Store at room temperature •Keep carton for important information.

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, polysorbate 60, polysorbate 80, cetyl esters, zinc

PCA, sodium PCA, aloe barbadensis leaf juice*, panthenol (pro-vitamin B5), tocopheryl acetate (vitamin E), glyceryl stearate, sorbic acid, sodium hyaluronate, sodium phytate, sodium hydroxide, cetyl potassium phosphate, xanthan gum, phenoxyethanol, ethylhexylglycerin. *Certified Organic Ingredient - Mayacert Certifier

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

Helps treat & prevent diaper rash

Helps seal out wetness

Dermatologist Tested

This maximum strength cream works quickly to help relieve everyday or hard-to-heal, stubborn diaper rash.

Stubborn diaper rash can be result of changes in diet, medication, or prolonged wetness.

Made with essential botanicals, vitamins, AP4[®] Organic Aloe^{*} Complex and clinically proven skin protectants, this soothing cream helps promote healing after the 1st use.

AP4[®] Organic Aloe^{*} Complex - proprietary soothing botanical blend

Colloidal Oats - helps soothe & relieve irritated skin

Shea Butter - soothes & moisturizes

Beeswax - calming properties

Zinc PCA - additional healing

Also try:

Stubborn Eczema Itch[™] Relief Cream

Aloe Healing & Cleansing Gel[™]

Daily Calming[™] Moisturizer

**Maximum Strength
Healing Botanicals**

Stubborn Diaper Rash[™] Relief Cream contains more healing power and is less sticky/goosey than most traditional diaper rash creams.

- **Works quickly**
- **Soothes tender skin**
- **Helps prevent diaper rash from recurring**

**Non-Greasy • No Added Fragrance
Free from Cortisone, Steroids & Parabens**

EXPERTS IN SKIN HEALING SINCE 1992

TriDerma MD[®] provides healing solutions for irritated skin without harmful side effects.

It all began after one woman struggled to find safe and effective healing for her own skin problem.

This journey led to the creation of our proprietary AP4[®] Organic Aloe* Complex which is key to all our products.

QUALITY YOU CAN FEEL, RESULTS YOU CAN SEE.[®]

Each product is made using this powerful complex plus nature's best botanicals and clinically proven ingredients.

We are passionate in our pursuit to create fast healing products that work.

Learn More at www.triderma.com

MADE IN THE USA

Dist. by: Genuine Virgin Aloe Corp., Corona, CA 92879 ©2019 0919

Packaging

Non Printing Area

TRIDERMA^{MD}
Baby™

Stubborn Diaper Rash™

Relief Cream

Helps treat & prevent diaper rash

Helps seal out wetness



Dermatologist Tested

Allantoin & Dimethicone
Skin Protectants

NET WT. 0.5 OZ (14g)

Drug Facts

Active ingredients	Purpose
Allantoin 1.5%	Skin Protectant
Dimethicone 2.0%	Skin Protectant

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■ Helps seal out wetness ■ Temporarily protects and helps relieve chafed, chapped or cracked skin

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

Dist. by: Genuine Virgin Aloe Corp., Corona, CA 92879
© 2019 Item 68505 0919 NDC 10738-068-55



Non Printing Area

Packaging

TRIDERMA^{MD}
Baby
Stubborn Diaper Rash™
Relief Cream

This maximum strength cream works quickly to help relieve everyday or hard-to-heal, stubborn diaper rash.

Stubborn diaper rash can be the result of changes in diet, medication, or prolonged wetness.

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www.triderma.com
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Baby
Stubborn Diaper Rash™
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Helps treat & prevent diaper rash
 Helps seal out wetness



Allantoin & Dimethicone
 Skin Protectants
 NET WT. 0.5 OZ (14g)

Item 68505
 NDC 10738-068-50

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Drug Facts (Cont.)	Do not use ■ On deep puncture wounds ■ On infections ■ On lacerations. When using this product ■ Avoid contact with eyes. If contact occurs, rinse thoroughly with water. 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 and contact a Poison Control Center right away.
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Drug Facts	Active ingredients Allantoin 1.5% Skin Protectant Dimethicone 2.0% Skin Protectant Purpose Skin Protectant Skin Protectant Uses ■ Helps treat and prevent diaper rash ■ Helps seal out wetness ■ Temporarily protects and helps relieve chafed, chapped or cracked skin Warnings For external use only
	Drug Facts (Cont.)

Drug Facts (Cont.)	(pro-vitamin B5), tocopheryl acetate (vitamin E), glyceryl stearate, sorbic acid, sodium hyaluronate, sodium phytate, sodium hydroxide, cetyl potassium phosphate, xanthan gum, phenoxethanol, ethylhexylglycerin. *Certified Organic Ingredient - Mayacert Certifier
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	Drug Facts (Cont.)

TRIDERMA^{MD}
Baby

Stubborn Diaper RashTM

Relief Cream

Helps treat & prevent diaper rash

Helps seal out wetness



Dermatologist Tested

Allantoin & Dimethicone

Skin Protectants

NET WT. 2.2 OZ (62g)

Maximum Strength Healing Botanicals

Drug Facts

Active ingredients

Allantoin 1.5%Skin Protectant
Dimethicone 2.0%Skin Protectant

Purpose

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www.triderma.com

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Item 68225 0919
NDC 10738-068-25



Packaging

TRIDERMA^{MD}
Baby
Stubborn Diaper Rash™
Relief Cream

EXPERTS IN
SKIN HEALING
SINCE 1992

TriDerma MD® provides healing solutions for irritated skin without harmful side effects.

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RESULTS YOU CAN SEE.®

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TRIDERMA^{MD}
Baby
Stubborn Diaper Rash™
Relief Cream

Stubborn Diaper Rash™
Relief Cream

Helps treat & prevent diaper rash

Helps seal out wetness



Dermatologist Tested



Allantoin & Dimethicone
Skin Protectants

NET WT. 2.2 OZ (62g)

Item 68225 NDC 10738-068-20



This maximum strength cream works quickly to help relieve everyday or hard-to-heal, stubborn diaper rash.

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Made with essential botanicals, vitamins, AP4® Organic Aloe* Complex and clinically proven skin protectants, this soothing cream helps promote healing after the 1st use.

AP4® Organic Aloe* Complex - proprietary soothing botanical blend

Colloidal Oats - helps soothe & relieve irritated skin

Shea Butter - soothes & moisturizes

Beeswax - calming properties

Zinc PCA - additional healing

Also try:
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Aloe Healing & Cleansing Gel™

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- ♥ Works quickly
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Free from Cortisone, Steroids & Parabens

Drug Facts

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

Packaging

TRIDERMA^{MD}
Baby

Stubborn Diaper Rash™

Relief Cream

Helps treat & prevent diaper rash

Helps seal out wetness



Dermatologist Tested

Allantoin & Dimethicone

Skin Protectants

NET WT. 4.0 OZ (113g)

Maximum Strength Healing Botanicals

Drug Facts

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



www.triderma.com

Dist. by: Genuine Virgin Aloe Corp.,

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Item 68045 0919 NDC 10738-068-45



Packaging

TRIDERMA^{MD}
Baby
Stubborn Diaper Rash™
Relief Cream

EXPERTS IN SKIN HEALING SINCE 1992

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TRIDERMA^{MD}
Baby
Stubborn Diaper Rash™
Relief Cream

Stubborn Diaper Rash™
Relief Cream

Helps treat & prevent diaper rash

Helps seal out wetness



Allantoin & Dimethicone
Skin Protectants

NET WT. 4.0 OZ (113g)

Item 68045 NDC 10738-068-40



This maximum strength cream works quickly to help relieve everyday or hard-to-heal, stubborn diaper rash.

Stubborn diaper rash can be the result of changes in diet, medication, or prolonged wetness.

Made with essential botanicals, vitamins, AP4® Organic Aloe* Complex and clinically proven skin protectants, this soothing cream helps promote healing after the 1st use.

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Colloidal Oats - helps soothe & relieve irritated skin

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Beeswax - calming properties

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Maximum Strength Healing Botanicals

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

TRIDERMA STUBBORN DIAPER RASH RELIEF

allantoin, dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10738-068
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)	
WHITE WAX (UNII: 7G1J5DA97F)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
OATMEAL (UNII: 8PI54V663Y)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SORBIC ACID (UNII: X045WJ989B)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POTASSIUM PHOSPHATE, TRIBASIC (UNII: 16D59922JU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
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:10738-068-50	1 in 1 CARTON	10/31/2019	

1	NDC:10738-068-55	14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10738-068-20	1 in 1 CARTON	10/31/2019	
2	NDC:10738-068-25	62 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:10738-068-40	1 in 1 CARTON	10/31/2019	
3	NDC:10738-068-45	113 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	10/31/2019	

Labeler - Genuine Virgin Aloe Corporation (961374147)

Establishment

Name	Address	ID/FEI	Business Operations
Genuine Virgin Aloe Corporation		961374147	manufacture(10738-068)

Revised: 2/2023

Genuine Virgin Aloe Corporation