

TRIDERMA PAIN RELIEF- lidocaine hcl, menthol 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 PAIN RELIEF CREAM

Drug Facts

Active ingredients

Lidocaine HCl 4.0%

Menthol 1.0%

Purpose

Topical Analgesic/Anesthetic

Uses temporarily relieves minor pain, itching and irritation due to/associated with:
•arthritis •simple backaches •muscle strain •sprains •bruises •minor cuts/scrapes

Warnings For external use only.

Ask a doctor before use if you have a heart condition.

Do not use •if you are allergic to any other type of numbing medicine •in large quantities, particularly over raw surfaces or blistered areas •on infections •on deep puncture wounds •if pregnant or breastfeeding.

When using this product •do not use over large skin areas •do not apply heat, bandages or plastic wrap to treated areas •do not use in or near the eyes •wash hands immediately after using.

Stop use and ask a doctor if •allergic reaction occurs •condition worsens or does not improve within 7 days •symptoms clear up and return within a few days •redness, irritation, swelling, pain or other symptoms begin or increase.

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

Directions • apply generously up to 3 to 4 times daily. For use on adults and children 12 years and older. Children under 12 - ask a doctor.

Inactive ingredients: water, caprylic/capric triglyceride, isopropyl palmitate, propanediol, glycerin, stearyl alcohol, butyrospermum parkii (shea) butter, acrylates/c10-30 alkyl acrylate crosspolymer, behenyl alcohol, tetrahydroxypropyl ethylenediamine, glyceryl stearate, peg-100 stearate, allantoin, cetearyl alcohol, cetareth-20, persea gratissima (avocado) oil, calophyllum inophyllum (tamanu) seed oil, polysorbate 60, aloe barbadensis leaf juice*, arnica montana flower extract, chamomilla recutita (matricaria) flower extract, hypericum perforatum (st. john's wort) flower/leaf/stem extract, boswellia serrata gum, sodium polyacrylate, hydrogenated polydecene, trideceth-6, phenoxyethanol, ethylhexylglycerin.*Certified Organic Ingredient - Mayacert Certifier

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

No Burning · Non-Greasy

Temporarily relieves minor aches & pains of muscles & joints from arthritis, simple backaches, strains, sprains & bruises

AP4 BOTANICAL

ALOE VERA COMPLEX

With Lidocaine HCl & Menthol

This specialized formula combines two proven maximum strength pain relievers, Lidocaine HCl and Menthol for minor relief of all types of aches and pains. It's ideal for Arthritis, simple backaches, muscle strains, bruises, minor cuts, scrapes, skin irritations and even insect bites.

Contains No Cortisone or Parabens

visit www.triderma.com

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

Made in USA

Pain Relief Cream is a unique formula that helps provide long-lasting comfort and fast pain relief.

It combines the best of nature's healing botanicals and science to help relieve pain, so that you can get on with your day.

· AP4[®] Aloe Vera Complex is a proprietary botanical blend made with Certified Organic Aloe Vera*.

· St. John's Wort, Arnica & Boswellia

· Contains a touch of Menthol for extra pain relief - light scent, disappears quickly.

Packaging

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· St. John's Wort, Arnica & Boswellia

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Questions?: 1-800-279-7282 or visit www.triderma.com



TRIDERMA MD

PAIN RELIEF CREAM

No Burning · Non-Greasy

Temporarily relieves minor aches & pains of muscles & joints from arthritis, simple backaches, strains, sprains & bruises



With Lidocaine HCl & Menthol

NET WT 2.0 OZ (57g)

This specialized formula combines two proven maximum strength pain relievers, Lidocaine HCl and Menthol for minor relief of all types of aches and pains. It's ideal for Arthritis, simple backaches, muscle strains, bruises, minor cuts, scrapes, skin irritations and even insect bites.

Contains No Cortisone or Parabens

Dist. by: Genuine Virgin Aloe Corp., Corona, CA 92879 © 2019
Made in USA Item 73021 0919 NDC 10738-073-20

LIFT FOR DRUG FACTS

Primary Display Panel

<p>Drug Facts</p> <p>Active ingredients</p> <p>Lidocaine HCl 4.0%.....Topical Analgesic/Anesthetic</p> <p>Menthol 1.0%.....Topical Analgesic/Anesthetic</p> <p>Purpose</p> <p>Temporarily relieves minor pain, itching and irritation due to/associated with:</p> <p>■arthritis ■simple backaches ■muscle strain ■sprains ■bruises ■minor cuts/scrapes</p> <p>Warnings For external use only.</p>	<p>Drug Facts (cont.)</p> <p>Ask a doctor before use if you have a heart condition.</p> <p>Do not use ■if you are allergic to any other type of numbing medicine ■in large quantities, particularly over raw surfaces or blistered areas ■on infections ■on deep puncture wounds ■if pregnant or breastfeeding.</p> <p>When using this product ■do not use over large skin areas ■do not apply heat, bandages or plastic wrap to treated areas ■do not use in or near the eyes ■wash hands immediately after using.</p>
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<p>Drug Facts (cont.)</p> <p>Stop use and ask a doctor if ■allergic reaction occurs ■condition worsens or does not improve within 7 days ■symptoms clear up and return within a few days ■redness, irritation, swelling, pain or other symptoms begin or increase.</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ apply generously up to 3 to 4 times daily. For use on adults and children 12 years and older. Children under 12 - ask a doctor.</p>	<p>Drug Facts (cont.)</p> <p>Inactive Ingredients: water, caprylic/capric triglyceride, isopropyl palmitate, propanediol, glycerin, stearyl alcohol, butyrospermum parkii (shea) butter, acrylates/c10-30 alkyl acrylate crosspolymer, behenyl alcohol, tetrahydroxypropyl ethylenediamine, glyceryl stearate, peg-100 stearate, allantoin, cetearyl alcohol, ceteareth-20, persea gratissima (avocado) oil, calophyllum tacamahaca (tamanu) seed oil, polysorbate 60, aloe barbadensis leaf juice*, amica montana flower extract, chamomilla recutita (matricaria) flower extract, hypericum perforatum (st. john's wort) flower/leaf/stem extract, boswellia serrata gum, sodium polyacrylate, hydrogenated polydecene, trideceth-6, phenoxyethanol, ethylhexylglycerin.</p> <p>*Certified Organic Ingredient - Mayacert Certifier</p> <p>Questions? 1-800-279-7282 M-F 8am-4pm PST</p>
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Packaging

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It combines the best of nature's healing botanicals and science to help relieve pain, so that you can get on with your day.

· AP4® Botanical Aloe Vera Complex is a proprietary blend made with Certified Organic Aloe Vera.

· St. John's Wort, Arnica & Boswellia

· Contains a touch of Menthol for extra pain relief - light scent, disappears quickly.



TRIDERMA MD

PAIN RELIEF CREAM

No Burning · Non-Greasy

Temporarily relieves minor aches & pains of muscles & joints from arthritis, simple backaches, strains, sprains & bruises



With Lidocaine HCl & Menthol

NET WT 4 OZ (113g)

This specialized formula combines two proven maximum strength pain relievers, Lidocaine HCl and Menthol for minor relief of all types of aches and pains. It's ideal for arthritis, simple backaches, muscle strains, bruises, minor cuts, scrapes and skin irritations.

Contains No Cortisone or Parabens

Questions: 1-800-279-7282 or visit www.triderma.com

Dist. by: Genuine Virgin Aloe Corp., Corona, CA 92879 © 2019
Made in USA ITEM 73041 0919 NDC 10738-073-41

LIFT FOR DRUG FACTS

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TRIDERMA PAIN RELIEF

lidocaine hcl, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10738-073
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DOCOSANOL (UNII: 9G1OE216XY)	
EDETOL (UNII: Q4R969U9FR)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALLANTOIN (UNII: 344S277G0Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
TAMANU OIL (UNII: JT3LVK84A1)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CHAMOMILE (UNII: FGL3685T2X)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
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:10738-073-20	1 in 1 CARTON	08/30/2019	
1	NDC:10738-073-21	57 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:10738-073-41	113 g in 1 JAR; Type 0: Not a Combination Product	08/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/30/2019	

Labeler - Genuine Virgin Aloe Corporation (961374147)

Establishment

Name	Address	ID/FEI	Business Operations
Genuine Virgin Aloe Corporation		961374147	manufacture(10738-073)

Revised: 2/2023

Genuine Virgin Aloe Corporation