

BURNZONE- pain relieving cream cream
MedZone Products LLC

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

Lidocaine HCl 1%

Purpose

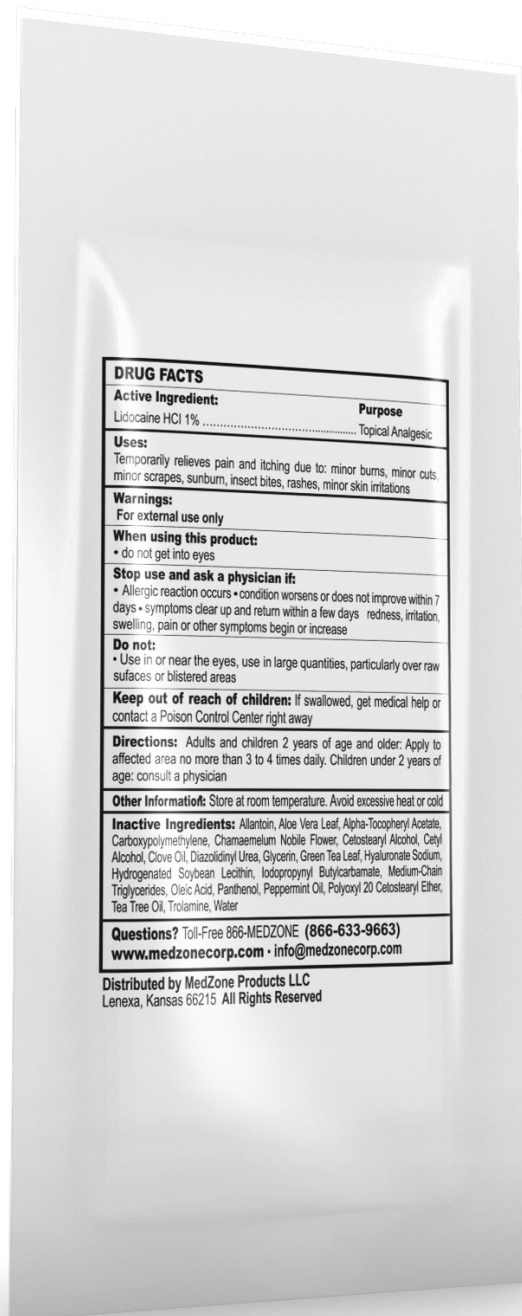
Topical Analgesic

Uses

Temporarily relieves pain and itching due to minor burns, minor cuts, minor scrapes, sunburn, insect bites, rashes, minor skin irritations.

Warnings

For external use only



DRUG FACTS	
Active Ingredient:	Purpose
Lidocaine HCl 1%	Topical Anesthetic
Uses:	
Temporarily relieves pain and itching due to: minor burns, minor cuts, minor scrapes, sunburn, insect bites, rashes, minor skin irritations	
Warnings:	
For external use only	
When using this product:	
• do not get into eyes	
Stop use and ask a physician 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	
Do not:	
• Use in or near the eyes, use in large quantities, particularly over raw surfaces or blistered areas	
Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center right away	
Directions: Adults and children 2 years of age and older: Apply to affected area no more than 3 to 4 times daily. Children under 2 years of age: consult a physician	
Other Information: Store at room temperature. Avoid excessive heat or cold	
Inactive Ingredients: Allantoin, Aloe Vera Leaf, Alpha-Tocopheryl Acetate, Carboxypolyethylene, Chamamelum Noble Flower, Cetostearyl Alcohol, Cetyl Alcohol, Clove Oil, Diazolidinyl Urea, Glycerin, Green Tea Leaf, Hyaluronate Sodium, Hydrogenated Soybean Lecithin, Isopropylmyl Butylcarbamate, Medium-Chain Triglycerides, Oleic Acid, Panthenol, Peppermint Oil, Polyoxy 20 Cetostearyl Ether, Tea Tree Oil, Triamine, Water	
Questions? Toll-Free 866-MEDZONE (866-633-9663)	
www.medzonecorp.com • info@medzonecorp.com	

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BURNZONE

pain relieving cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70338-621
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
OLEIC ACID (UNII: 2UMI9U37CP)	
PANTHENOL (UNII: WV9CM0O67Z)	
TEA TREE OIL (UNII: VIF565UC2G)	
CLOVE OIL (UNII: 578389D6D0)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALLANTOIN (UNII: 344S277G0Z)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70338-621-12	3.6 g in 1 POUCH; Type 0: Not a Combination Product	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2016	

Labeler - MedZone Products LLC (080083739)

Registrant - Richard Hamer Associates LLC (067731889)

Establishment

Name	Address	ID/FEI	Business Operations
Biomed Laboratories LLC		055329696	manufacture(70338-621) , pack(70338-621)

Establishment

Name	Address	ID/FEI	Business Operations
Microconsult Inc.		062183608	analysis(70338-621)

Establishment

Name	Address	ID/FEI	Business Operations
Ceutical Laboratories Inc.		789485153	analysis(70338-621)

Revised: 2/2018

MedZone Products LLC