ZONE 1- lidocaine hcl cream
Dermal Source, Inc.

Drug Facts - For use by licensed professionals only.

Active Ingredients (in each cc)	Purpose
Lidocaine HCl 4%	Topical Anesthetic

Indications: Temporarily relieves pain associated with anorectal disorders.

Warnings: **Do not swallow. Keep out of children's reach. External use only on intact skin.**

Do not use if pregnant or breast-feeding.
Do not use if you have seizures or liver disease.
Do not use if you have a known allergy or sensitivity to any component of this product. If sensitivity occurs, discontinue use, immediately cleanse skin and seek medical attention. If condition worsens or if symptoms persist for more than seven days or clear up and occur again, discontinue use and consult a doctor. Do not use in large quantities, particularly over raw surfaces or blistered areas. Avoid contact with eyes. In case of contact with eyes, rinse immediately with copious amounts of eyewash and seek treatment by a medical professional. If accidentally swallowed, get medical attention immediately.

Directions: Sensitivity test advised prior to use.

Apply a moderately thick layer of cream to intact skin. Discontinue use if sensitivity occurs. Wait for numbness to develop. For thinner skin (eye area) wait 10-15 minutes. For thicker skin, best results are obtained after 1 hour of application. Cleanse area thoroughly before procedure.

Inactive Ingredients: Purified Water, Glyceryl Stearate (and) PEG 100-Stearate, Petrolatum, Stearic Acid, Cetyl Alcohol, Xanthan Gum, Glycerol Monostearate, Sodium Hydroxymethlyglycinate, Triethanolamine, Propyl Paraben, Methyl Paraben, and BHT.

Other information: Store in a cool dark place or refrigerate. Discard by expiration date.

Questions? Contact distributor on product label for further questions.

PRINCIPAL DISPLAY PANEL

MAXIMUM

Zone 1
TOPICAL ANALGESIC

7 pH

1/2 oz.

4% Lidocaine Cream

for use before a
pain sensitive procedure

Distributed by: DERMAL SOURCE
Portland, OR 97232

www.dermalsource.com
1-866-568-3223

NDC 80069-014-01

ZONE 1
lidocaine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80069-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Peg-100 Stearate (UNII: YD01N1999R)	
Petrolatum (UNII: 4T6H12BN9U)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Xanthan Gum (UNII: TTV12P4NEE)	
Sodium Hydroxymethylglycinate (UNII: DIG6BWZ9XT)	
Trolamine (UNII: 9O3K93S3TK)	
Propylparaben (UNII: Z8IX2SC1OH)	
Methylparaben (UNII: A2I8C7HI9T)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80069-014-01	14.1748 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	11/01/2004	

Labeler - Dermal Source, Inc. (183535629)

Establishment

Name	Address	ID/FEI	Business Operations
HTO Nevada, Inc. (dba Kirkman)		117115846	manufacture(80069-014)

Revised: 5/2024 Dermal Source, Inc.