ZONE 2- lidocaine hcl, epinephrine gel
Dermal Source, Inc.

Drug Facts - For use by licensed professionals only.

Active Ingredients (in each cc)		***Purpose***
Lidocaine HCL	5%	Topical Anesthetic
Epinephrine	0.01%	Vasoconstrictor

Uses: Temporarily relieves local pain and swelling on irritated hemorrhoidal tissue or other anorectal disorders.

WARNINGS: External use only.
Do not swallow. Keep out of children's reach.

Do not use if you have
- A history of sever liver disease or impairment.
- A known allergy or sensitivity to any of the components of this product. If sensitivity occurs, consult a doctor if condition worsens or does not improve in seven days, or clears up and occurs again within a few days. Do not use in large quantities, particularly over raw surfaces or blistered areas.

Do not use if pregnant or nursing. In case of accidental contact with eyes, rinse immediately with copious amounts of eyewash. Seek care by an eye care physician. If accidentally swallowed, get medical help immediately.

When using this product
- You may notice temporary blanching, skin irritation or sensitivity of the skin where gel is applied
- You may not have pain - avoid sources of heat or injury
- You may have delayed swelling after drug is dissipated

Directions: Sensitivity test advised prior to use.

Apply sparingly to affected area up to four times daily and cover with occlusive dressing. Product is ineffective when applied to intact skin. Wait until anesthetic effect occurs (2-5 minutes). Remove product.

Inactive Ingredients: Purified Water, Ethoxydiglycol, Propylene Glycol, Hydroxyethylcelluse, Sodium Metabisulfite, Diazolidinyl Urea, Disodium EDTA, Methyl Paraben, Propyl Paraben, and Citric Acid.

***Other information*:** Store in a cool dark place or refrigerate. Discard after expiration

date.

Questions? Contact distributor on product label for further questions.

PRINCIPAL DISPLAY PANEL

NDC Code: 80069-012-01

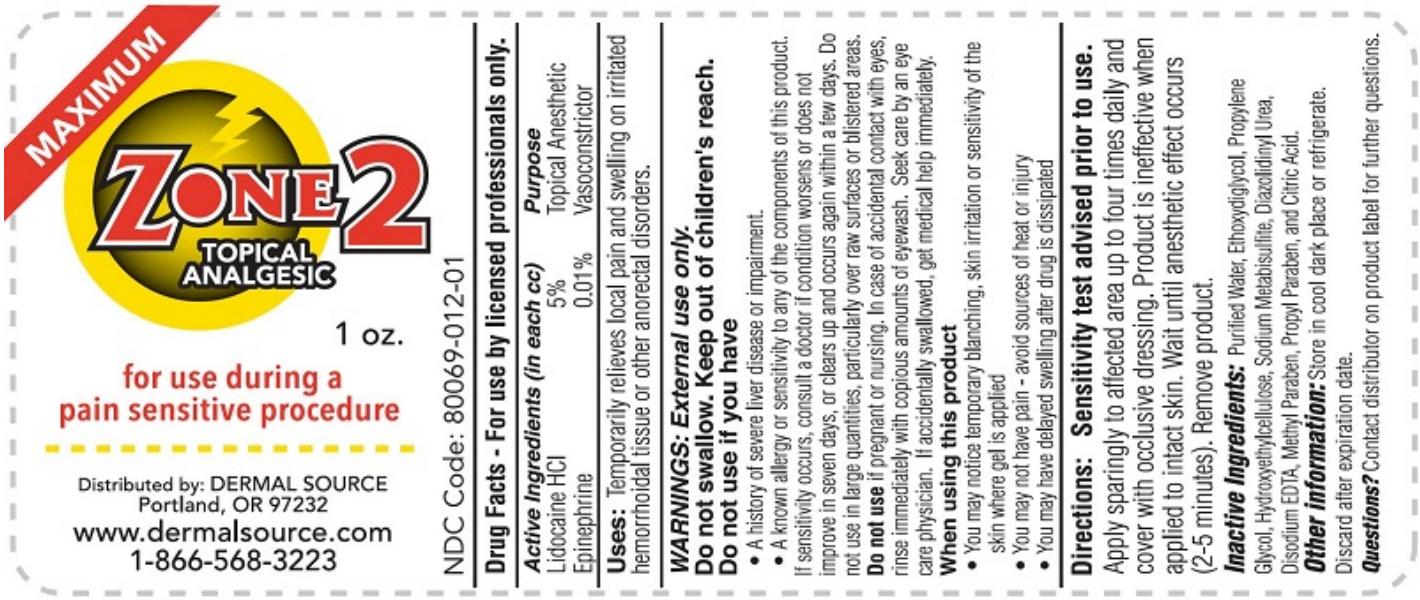
MAXIMUM
Zone 2

TOPICAL ANALGESIC

1 oz.

for use during a pain sensitive procedure

Distributed by: **DERMAL SOURCE**
Portland, OR 97232
www.dermalsource.com
1-866-568-3223



ZONE 2

lidocaine hcl, epinephrine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80069-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	50 mg in 1 mL
Epinephrine (UNII: YKH834O4BH) (Epinephrine - UNII:YKH834O4BH)	Epinephrine	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Diethylene Glycol Monoethyl Ether (UNII: A1A1I8X02B)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Hydroxyethyl Cellulose, Unspecified (UNII: T4V6TWG28D)	
Sodium Metabisulfite (UNII: 4VON5FNS3C)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80069-012-01	29.5735 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2022	06/24/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	04/01/2022	06/24/2024

Labeler - Dermal Source, Inc. (183535629)

Establishment

Name	Address	ID/FEI	Business Operations
HTO Nevada, Inc. (dba Kirkman)		117115846	manufacture(80069-012)

Revised: 5/2024 Dermal Source, Inc.