LIDOCAINE HCL 4% MENTHOL 1%- lidocaine hcl 4% menthol 1% ointment
OPMX 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.

CalmaDrazos

Lidocaine HCl 4% and Menthol 1%

Lidocaine HCl 4%

Menthol 1%

benzyl alcohol, carbomer, hydrogenated lecithin, polysorbate 80, propylene glycol, purified water triethanolamine, vitamin E

Adults and children 12 years and older: apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 to 4 applications in a 24-hour period.

BEFORE AND AFTER APPLYING, WASH HANDS WITH SOAP AND WATER.

Children under 12 years: ask a doctor

temporary relieves minor pain

For external use only

Do not use on large areas of the body or on cut, irritated or swollen skin, on puncture wounds, for more than one week without consulting a doctor.

When using this product use only as directed. Read and follow all directions and warnings on this label, rare cases of serious burns have been reported with products of this type, do not bandage or apply local heat (such as heating pads) to the area of use or use with a medicated, avoid contact with eyes and mucous membranes, a transient burning sensation may occur upon application but generally disappears in several days.

Stop use and ask a doctor if condition worsens, redness is present, irritation develops, symptoms persist for more than 7 days or clear up and occur again within a few days, you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away.

Topical anesthetic

Topical analgesic

NDC: 69729-452-72 Calmadrazos

LIDOCAINE HCL 4% MENTHOL 1%

lidocaine hcl 4% menthol 1% ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69729-452
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-452-72	76.6 g in 1 PACKAGE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2020	

Labeler - OPMX LLC (029918743)

Revised: 6/2022 OPMX LLC