INKEEZE ORIGINAL B NUMB CYLINDER- lidocaine gel Indelicare, 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.

Inkeeze Original Numb Professional Numbing Gel Cylinder

DRUG FACTS

ACTIVE INGREDIENTS:

Lidocaine 5%

PURPOSE:

Topical Anesthetic

USES:

External Use Only: For the temporary relief of local itching and discomfort in the perianal area.

INACTIVE INGREDIENTS:

Alcohol, Benzyl Alcohol Carbomer, Citric Acid, Ethoxydiglycol, Propylene Glycol, Purified Water.

DIRECTIONS:

Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly or by patting with an appropriate cleansing pad. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.

KEEP OUT OF REACH OF CHILDREN

If condition worsens or does not improve within 7 days, consult a doctor. Do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, consult a doctor promptly. Do not put this product into the rectum by using fingers or any mechanical device or applicator. Certain persons can develop allergic reactions to ingredients in this product. If the symptoms being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

WHEN USING THIS PRODUCT:

you may notice temporary blanching or redness of the skin where gel is applied.

CONTACT:

1-800-611-7720 www.inkeeze.com

Package Labeling:



lidocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82022-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:82022-001- 00	29.5 mL in 1 TUBE; Type 0: Not a Combination Product	08/12/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	08/12/2021	

Labeler - Indelicare, LLC (118075123)

Revised: 8/2021 Indelicare, LLC