

INKEEZE ORIGINAL B NUMB- 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

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:



INKEEZE ORIGINAL B NUMB			
lidocaine gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82022-000
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: A1A118X02B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82022-000-00	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