

NUMB520- lidocaine hydrochloride cream
Clinical Resolution Laboratory, Inc.

Numb520

DRUG FACTS

Active Ingredient

Lidocaine HCl 5%

Purpose

Local Anesthetic

Uses:

for the temporary relief of local and anorectal discomfort associated with anorectal disorders or inflammation.

Warnings

(For external use only)

Do not use this product if

- pregnant or breastfeeding, ask a health professional before use.
- in case of accidental overdose, get medical help or contact the Poison Control Center immediately.
- tamper evident "Do not use this product" if seal is broken or missing.

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor.
- certain persons can develop allergic reactions to ingredients in this product.
- do not put this product into the rectum by using finger or any medical device or applicator.

Stop use and ask a doctor if

the symptom being treated does not subside, or if redness, irritation, swelling, pain, or other symptoms develop or increase

Keep out of reach of children

In case of accidental ingestion, seek medical attention immediately.

Directions

- *Adults:* When practical, cleanse the affected area with mild soap and warm water and

rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth, before application of this product.

- Apply up to 6 times a day.
- Children under 12 years of age: consult a doctor.

Other Information

- keep away from direct sunlight or heat.
- store in room temperature (59-86°F/15-30°C)

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Dimethyl Isosorbide, Disodium EDTA, Hydrogenated Polydecene, Lecithin, Neopentyl Glycol Dicaprylate/Dicaprate, Propylene Glycol, Purified Water, Sodium Polyacrylate, Tocopheryl Acetate, Trideceth-6, Triethanolamine

Package Labeling:

ColorBuild 100/10/29/20

R359_2.25x6 in

Manufactured for Ebanel Laboratories, Inc.
1400 W. Lambert Rd. Suite D • Brea CA 92821
www.Ebanel.com | Made in USA

VZ2
337807
682017




CHILD PROOF PACKAGING

Topical Anesthetic Cream

4.4 oz e 125g

DRUG FACTS	
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Lidocaine HCl 5%	Local Anesthetic
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Package Labeling: (63742-030-01)



Manufactured for Ebanel Laboratories, Inc.
1400 W. Lambert Rd., Suite D-Brea, CA 92821 | www.Ebanel.com | Made in USA

DRUG FACTS (Continued)

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CHILD PROOF PACKAGING

Topical Anesthetic Cream

1.38 oz e 39g

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NUMB520

lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63742-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALLANTOIN (UNII: 344S277G0Z)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
TROLAMINE (UNII: 903K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63742-030-00	125 g in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2019	
2	NDC:63742-030-01	39 g in 1 JAR; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	09/12/2019	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Establishment

Name	Address	ID/FEI	Business Operations
Clinical Resolution Laboratory, Inc.		825047942	manufacture(63742-030) , label(63742-030) , pack(63742-030)

Revised: 12/2023

Clinical Resolution Laboratory, Inc.