NUMB520- lidocaine hydrochloride cream Clinical Resolution Laboratory, Inc.

Numb520

DRUG FACTS

Active Ingredient

Lidocaine HCI 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.

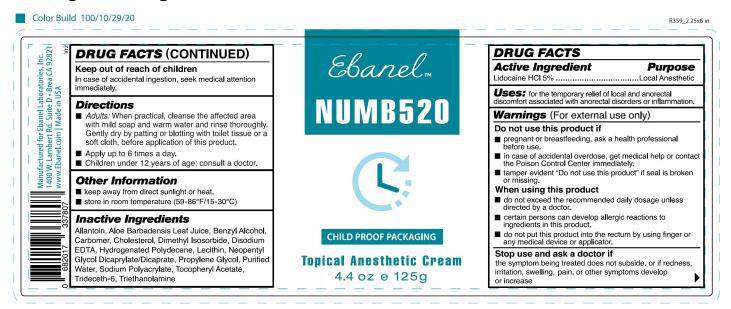
Other Information

- 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:



Package Labeling: (63742-030-01)



DRUG FACTS (Continued)

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Ebanel NUMB520



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)	
.ALPHATOCOPHEROL 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.