NUMB25- lidocaine cream Clinical Resolution Laboratory, Inc.

Numb25

DRUG FACTS

Active Ingredient

Lidocaine 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.
- 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.

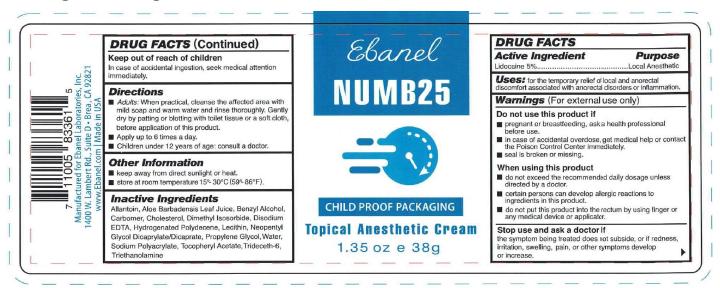
Other Information

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

Inactive Ingredients

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

Package Labeling:63742-035-01



Package Labeling:63742-035-02



DRUG FACTS (Continued)

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, Water, Sodium Polyacrylate, Tocopheryl Acetate, Trideceth-6, Triethanolamine





CHILD PROOF PACKAGING

Topical Anesthetic Cream 4.4 oz e 125g

DRUG FACTS

Active Ingredient

Purpose

Lidocaine 5%.....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

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

NUMB25

lidocaine cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63742-035

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
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)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	

Packaging

TROLAMINE (UNII: 903K93S3TK)

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63742-035- 01	38 g in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2018	
2	NDC:63742-035- 02	125 g in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2018	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M015	10/04/2018			

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 5/2025 Clinical Resolution Laboratory, Inc.