

ETADERM NUMBING CREAM- lidocaine cream
NUEPHASE LLC

ETADERM Numbing Cream

Active Ingredients

Lidocaine 5 %

Purpose

Local Anesthetic

Uses:

For temporary relief of local and Anorectal discomfort associated with Anorectal discomfort or inflammation

Warnings:

For external use only

When using this product

- ■ do not get into eyes. ■ do not exceed the recommended daily dosage unless directed by a doctor ■ do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

- ■ condition worsens or does not improve within 7 days. ■ in case of bleeding, consult a doctor promptly ■ Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding,

ask a health professional before use

Directions:

■ Cleanse affected area and gently dry. Apply externally to the affected area up to 6 times daily, especially at night, in the morning or after each bowel movement ■ Children under 12 years of age: consult a doctor.

Inactive Ingredients:

Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine, Vitamin E Acetate.

Questions?

424-354-4370



ETADERM

NUMBING

CREAM

 Made with

 -cham ingredients

 Net Wt. 1.5oz (44g)

Drug Facts

Active Ingredients	Purpose
Lidocaine 5%	Local Anesthetic

Uses For temporary relief of local and internal discomfort associated with hemorrhoids or inflammation.

Warnings For external use only.

When using this product - do not get into eyes. • do not exceed the recommended daily dosage unless directed by a doctor • do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if • condition worsens or does not improve within 7 days, • in case of bleeding, consult a doctor promptly • Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get help or contact a Poison Control Center right away.

Directions • Cleanse affected area and gently dry. Apply externally to the affected area up to 5 times daily, especially at night, in the morning or after each bowel movement • Children under 12 years of age, consult a doctor.

Inactive ingredients Benzyl Alcohol, Carbomer, Cholesterol, Hydroxyethyl Cellulose, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trijamine, Vitamin E Acetate.

Questions? 424-354-4370

Manufactured for:
EtaDerm
 Miami, Florida, 33139
www.eta Derm.com





 MADE IN USA

 with US & Imported materials

ETADERM NUMBING CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84180-001	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	5 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CARBOMER (UNII: 0A5MM307FC)				
CHOLESTEROL (UNII: 97C5T2UQ7J)				
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 9O3K93S3TK)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84180-001-01	44 g in 1 TUBE; Type 0: Not a Combination Product	07/15/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	07/15/2022		

Labeler - NUEPHASE LLC (118900101)

Registrant - Bridgeview Investments LLC (035014854)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC		081030372	manufacture(84180-001)