NUPHARMISTO- lidocaine cream
Orange Lab, Inc

Nupharmisto Lidocaine Numbing Cream 5%

Drug Facts

Purpose

Uses: For the temporary alleviation of localized discomfort, Itching, pain, or burning sensation in the perianal area associated with anorectal disorders.

Warnings

Warnings ■ For external use only. ■ Avoid contact with the eyes.
■ If allergic reaction occurs, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

When using this product

When using this product do not exceed the recommended daily dosage unless directed by a doctor. Avoid inserting this product into the rectum using fingers, medical devices, or applicators. Do not use if you are allergic to the ingredients in this product or if the seal is broken or missing.

Stop use and ask a doctor if

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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In case of accidental ingestion, seek medical attention immediately.

How to use it correctly?

HOW TO USE IT CORRECTLY?

1. Clean your hands and treatment area thoroughly with mild soap and warm water. Gently dry them afterward.
2. Apply a thick layer of numbing cream to the treatment area, making sure to cover both the treatment area and its surroundings.
3. After 5 minutes to get relief, leave it on for 40-50 minutes for the best results (keeping it on longer gives better effects).
4. Remove excess cream and wait an additional 10 minutes for the numbing sensation to reach its peak.

Note: The duration of numbness may vary depending on temperature and individual skin types. It's recommended to perform a small patch test for the best numbing effect

Inactive Ingredients

Inactive ingredients: Di Water, Dimethyl Isosorbide, Ethylhexyl Palmitate, Hydrogenated Polydecene, Propylene Glycol, Arnica Montana Flower Extract, Helianthus Annuus (Sunflower) Seed Oil, Emu Oil, Phenoxyethanol, Sodium Polyacrylate, Trideceth-6, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Tocopheryl Acetate, Ethylhexylglycerin, Tetrasodium Edta

Other information : storage

Other information: * Store room temperature 59°-86°F (15°-30°C).
*Keep away from direct sunlight or heat.

Directions for use

Directions ■ **Children under 2 years**: Do not use.
- **For children under 12**: Consult a doctor.
- **For adults**: Apply to affected area not more than 6 times daily. Clean the affected area with mild soap and warm water, making sure to rinse thoroughly. Gently dry the area with toilet tissue or a soft cloth before applying the product.

Active ingredient and directions

DRUG FACTS

Active Ingredient	***Purpose***
Lidocaine 5%	Local Anesthetic
Menthol 0.7%	Local Anesthetic

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Usage section

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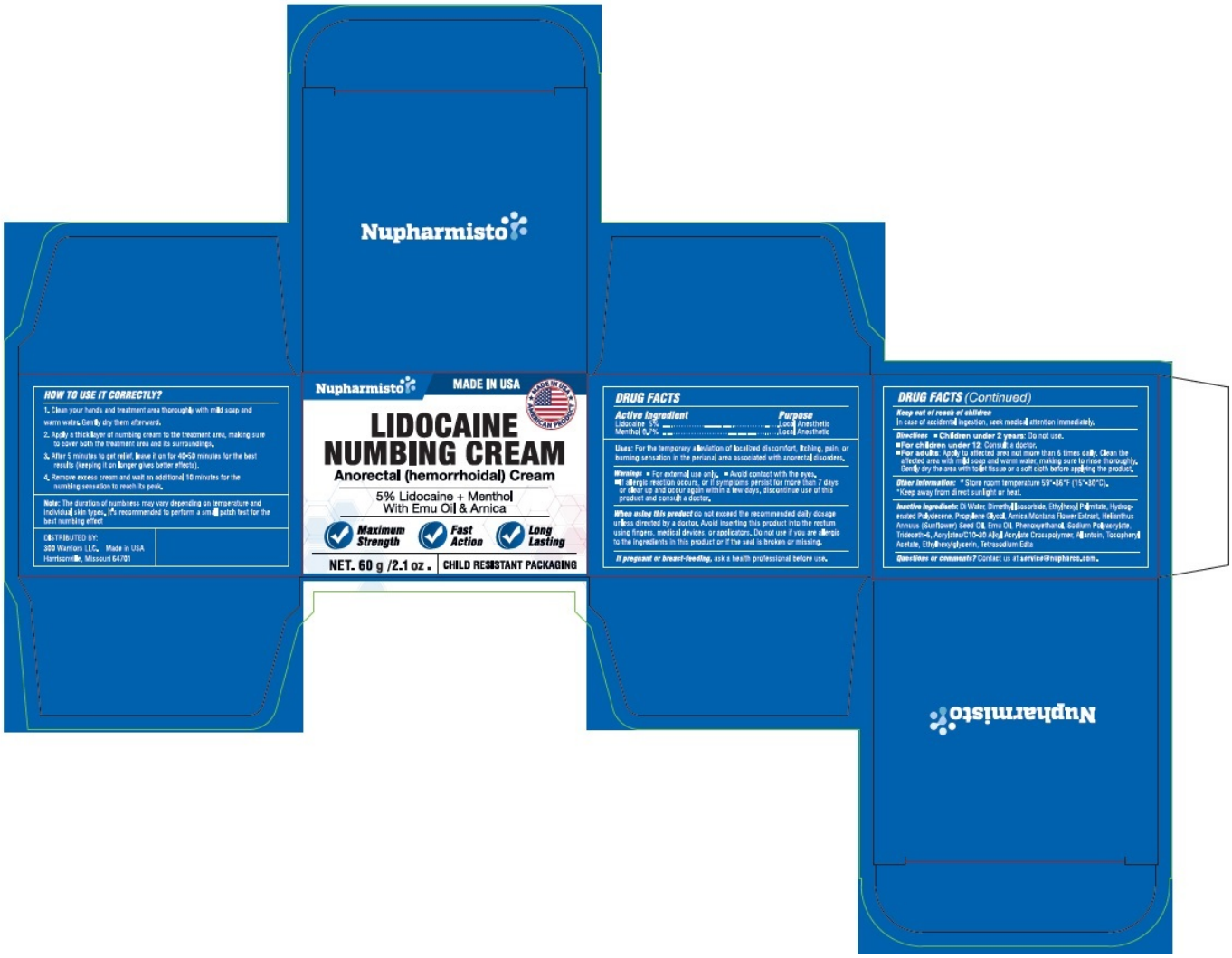
Label Images



NUPHARMISTO

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71331-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.7 g in 100 g

LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EMU OIL (UNII: 344821WD61)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
HYDROGENATED POLYDECENE (1500 CST) (UNII: 4YI0729529)	
SUNFLOWER OIL UNSAPONIFIABLES (UNII: T7ZE2WA4MB)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71331-113-05	60 g in 1 PACKAGE; Type 0: Not a Combination Product	03/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	03/01/2024	

Labeler - Orange Lab, Inc (004862271)

Revised: 2/2024 Orange Lab, Inc