NUMB520- lidocaine, phenylephrine hydrochloride spray
Clinical Resolution Laboratory, Inc.

Numb520 SPRAY

DRUG FACTS

Active Ingredient

Lidocaine 5%

Phenylephrine HCL 0.25%

Purpose

Local Anesthetic

Vasoconstrictor

Uses:

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

Warnings

- for external use only.
- avoid contact with the eyes.

keep out of reach of children.

Do not use

this product if

- pregnant or breastfeeding, ask a health professional before use.
- seal is broken or missing.
- you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of prostate gland unless directed by a doctor.

When using this product

- do not exceed the recommended daily usage.
- 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.
- if swallowed, call your Poison Control Center at 1(800) 222 1222.
- If condition worsens or does not improve within 7 days, consult a doctor.

Stop use and ask a doctor if

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

Directions

- clean the affected area.
- sensitivity and possible allergy tests advised prior to use. Spray sparingly to affected area after thoroughly cleansing. Wait until anesthetic effect occurs. You may reapply to continue numbing effect.
- apply to the affected area up to 4 times daily.
- children under 12 years of age: consult a doctor.

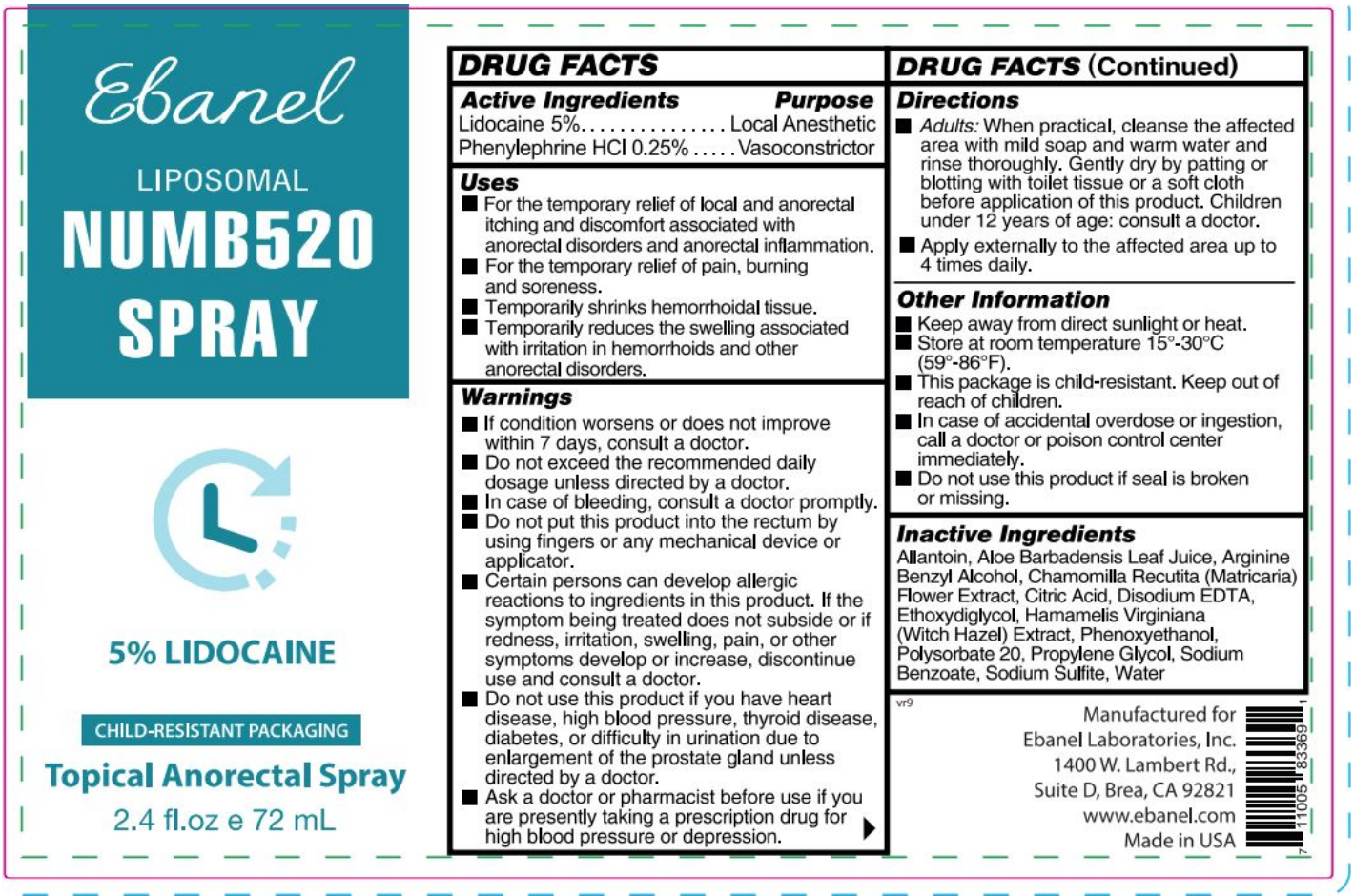
Other Information

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

Inactive Ingredients

Allantoin, Arginine, Benzyl Alcohol, Disodium EDTA, Ethoxydiglycol, Phenoxyethanol, Polysorbate 20, Water, Sodium Benzoate, Sodium Sulfite

Package Labeling:



NUMB520

lidocaine, phenylephrine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63742-034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ARGININE (UNII: 94ZLA3W45F)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM SULFITE (UNII: VTK01UQK3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63742-034-01	72 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	11/26/2018	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 5/2025 Clinical Resolution Laboratory, Inc.