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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Numb520 Spray

DRUG FACTS

Active Ingredients

Lidocaine HCL 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.
- Tamper Evident "Do not use this product" if safety 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 fingers 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 spraingly 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.

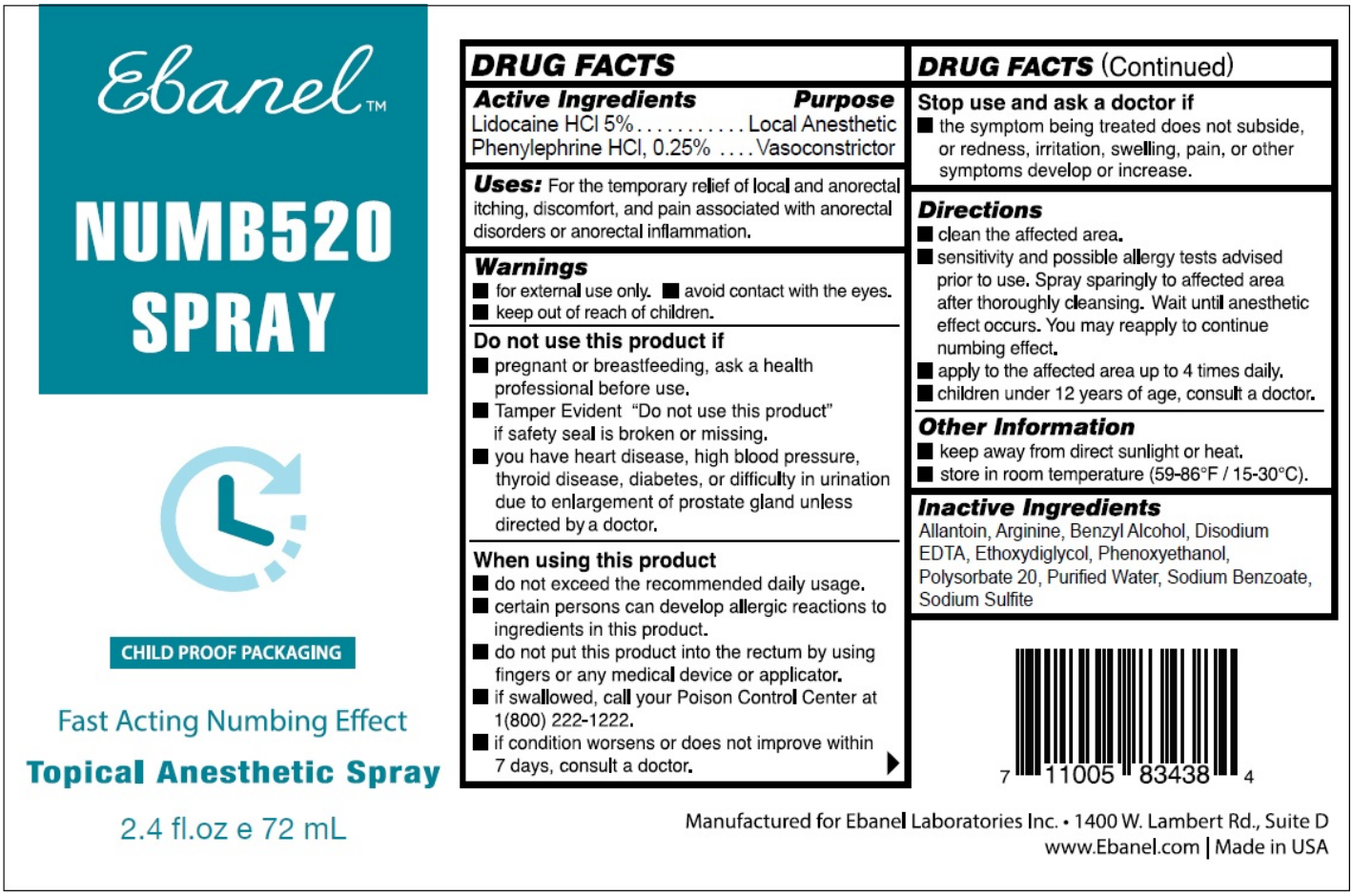
Other Information

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

Inactive Ingredients

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

Package Labeling:



NUMB520

lidocaine hydrochloride, phenylephrine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63742-012
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 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:63742-012-00	72 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	05/01/2019	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 5/2019 Clinical Resolution Laboratory, Inc.