

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:

<p><i>Ebanel</i> LIPOSOMAL NUMB520 SPRAY</p>	<p>DRUG FACTS</p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Lidocaine 5%.....</td> <td>Local Anesthetic</td> </tr> <tr> <td>Phenylephrine HCl 0.25%</td> <td>Vasoconstrictor</td> </tr> </table>	Active Ingredients	Purpose	Lidocaine 5%.....	Local Anesthetic	Phenylephrine HCl 0.25%	Vasoconstrictor	<p>DRUG FACTS (Continued)</p>
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Lidocaine 5%.....	Local Anesthetic							
Phenylephrine HCl 0.25%	Vasoconstrictor							
 <p>5% LIDOCAINE</p>	<p>Uses</p> <ul style="list-style-type: none"> ■ For the temporary relief of local and anorectal itching and discomfort associated with anorectal disorders and anorectal inflammation. ■ For the temporary relief of pain, burning and soreness. ■ Temporarily shrinks hemorrhoidal tissue. ■ Temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders. 	<p>Directions</p> <ul style="list-style-type: none"> ■ <i>Adults:</i> 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. Children under 12 years of age: consult a doctor. ■ Apply externally to the affected area up to 4 times daily. 						
<p>CHILD-RESISTANT PACKAGING</p> <p>Topical Anorectal Spray</p> <p>2.4 fl.oz e 72 mL</p>	<p>Warnings</p> <ul style="list-style-type: none"> ■ If condition worsens or does not improve within 7 days, consult a doctor. ■ Do not exceed the recommended daily dosage unless directed by a doctor. ■ In case of bleeding, consult a doctor promptly. ■ Do not put this product into the rectum by using fingers or any mechanical device or applicator. ■ 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. ■ Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor. ■ Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression. 	<p>Other Information</p> <ul style="list-style-type: none"> ■ Keep away from direct sunlight or heat. ■ Store at room temperature 15°-30°C (59°-86°F). ■ This package is child-resistant. Keep out of reach of children. ■ In case of accidental overdose or ingestion, call a doctor or poison control center immediately. ■ Do not use this product if seal is broken or missing. 						
		<p>Inactive Ingredients</p> <p>Allantoin, Aloe Barbadensis Leaf Juice, Arginine, Benzyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Disodium EDTA, Ethoxydiglycol, Hamamelis Virginiana (Witch Hazel) Extract, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium Benzoate, Sodium Sulfite, Water</p> <p>Manufactured for Ebanel Laboratories, Inc. 1400 W. Lambert Rd., Suite D, Brea, CA 92821 www.ebanel.com Made in USA</p> 						

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: A1A18X02B)	
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)