LIDOFORTE HEMORRHOIDAL- lidocaine mineral phenylephrine hydrochloride petrolatum cream
Satius Pharmaceuticals, LLC

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.

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lidoForte Hemorrhoidal Cream

DRUG FACTS

Active Ingredients

Lidocaine 5% w/w

Mineral Oil 17% w/w

Phenylephrine HCI 0.25% w/w

White Petrolatum 39% w/w

Purpose

Local anesthetic

Protectant

Vasoconstrictor

Protectant

Uses:

- Helps relieve the pain, itching and burning associated with hemorrhoids
- Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders
- Temporarily provides a coating for relief of anorectal discomforts
- Temporarily protects irritated areas and inflamed perianal skin

Warnings

For external use only.

Ask a doctor before use if you have:

- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes
- Difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug for high blood pressure or depression

When using this product

- Avoid contact with eyes

- Do not exceed 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

- Bleeding occurs
- Condition worsens or does not improve within 7 days
- Allergic reaction occurs to ingredients in this product
- Symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

If pregnant or breastfeeding,

ask a doctor before use.

Keep out of reach of children.

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

Directions

- 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 soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 4 times daily
- Children under 12 years of age: consult a doctor
- **To use finger cots:** Roll one finger cot over finger. Gently squeeze cream onto finger cot. Smooth a layer of the cream over affected area.

Other information

Store at 25 degrees C (77 Degrees F); excursions permitted to 15-30 degrees C (59-86 degrees F) [see USP Controlled Room Temperature].

Inactive ingredients

Aqua (purified water), Benzyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Citric Acid, Dehydroacetic Acid

Package Labeling:

Lidocaine 5%
Phenylephrine HCl 0.25%

Shrinks swollen hemorrhoidal tissue

Relieves pain, itch and irritation

Dual action: soothes and protects

Dispensed Only By Physicians

satius PHARMACEUTICALS

NET WT 1.5 oz

PROFESSIONAL

discomforts
- Temporarily protects irritated areas and inflamed perianal skin

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Distributed by: Satius Pharmaceuticals
PO Box 1641, Wall, NJ 07719
www.satiusrx.com

NON PRINTING AREA

LIDOFORTE HEMORRHOIDAL

lidocaine mineral phenylephrine hydrochloride petrolatum cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71890-310
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
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	170 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	25 mg in 1 mL
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	390 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71890-310-01	1 in 1 BOX	11/18/2017	
1		44.3603 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/18/2017	

Labeler - Satius Pharmaceuticals, LLC (080518631)

Revised: 11/2017 Satius Pharmaceuticals, LLC