HEMORRHOIDAL RELIEF CREAM- lidocaine cream
CURETECH SKINCARE

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.

Hemorrhoidal Relief Cream

Drug Facts

Active ingredients

Lidocaine USP 4%

Phenylephrine HCL USP 0.25%

Purpose

Lidocaine USP 4%----------Local Anesthetic

Phenylephrine HCL USP 0.25%--Vasoconstrictor

Uses

- Helps relieve the anorectal symptoms associated with hemorrhoids (pain, soreness, burning)
- Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders

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

- do not exceed recommended daily usage 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
- an allergic reaction develops
- if symptoms being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

If pregnant or breast-feeding

ask a healthcare professional before use

Keep out of reach of children:

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

Directions

- **adults:** when possible, clean affected area with mild soap or warm water, rinse thoroughly, and then gently dry (patting or blotting) with tissue or soft cloth before use
- to use dispensing cap, attach it to the tube, lubricate well, then gentle insert part way into anus and squeeze tube to deliver medication. Thoroughly cleanse dispensing cap after use with mild soap and warm water and rinse thoroughly
- apply to affected area upto 4 times daily, especially at night, when waking up and after each bowel movement

Children under 12 years of age: ask a doctor

Other information

- store at 59 to 77 F to avoid melting

Inactive ingredients

.Alpha.-Tocopherol Acetate, Aloe Vera Leaf, Asian Ginseng, Calendula officinalis Flower, Chamomile, Chlorocresol, Cholecalciferol, Coconut Oil, Corn Oil, Dimethicone, Fragrance, Hyaluronate Sodium, Hydrocortisone, Lysine Hydrochloride, menthol, Mineral Oil, Petrolatum, Propylene Glycol, Pyridoxine Hydrochloride, Sunflower Oil, Tricaprilin, Vitamin A Palmitate, yellow Wax, Zinc Oxide

Principal Display & Drug Fact Panel

HEMORRHOIDAL RELIEF CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73622-3077
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
CHAMOMILE (UNII: FGL3685T2X)	
CHLOROCRESOL (UNII: 36W53O7109)	

CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CORN OIL (UNII: 8470G57WFM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
COCONUT OIL (UNII: Q9L0O73W7L)	
HYDROCORTISONE (UNII: WI4X0X7BPJ)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRICAPRILIN (UNII: 6P92858988)	
MENTHOL (UNII: L7T10EIP3A)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73622-3077-5	28.3 g in 1 TUBE; Type 0: Not a Combination Product	03/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/04/2021	

Labeler - CURETECH SKINCARE (677682180)

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