LIPOSOMAL HEMORRHOID MASTER- lidocaine , phenylephrine hcl cream
Clinical Resolution Laboratory, Inc.

DRUG FACTS

Active Ingredients	***Purpose***
Lidocaine 5%	Local Anesthetic
Phenylephrine Hcl 0.25%	Vasoconstrictor

Uses:

- 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.

Warnings

- **For external and / or intrarectal use only.**
- 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.
- 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.
- Do not use this product with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a doctor promptly.

Directions

- Adults: 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.
- **For External use**: Apply externally to the affected area up to 4 times daily.
- **For Intrarectal use**: Attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Apply to the affected area up to 4 times daily.

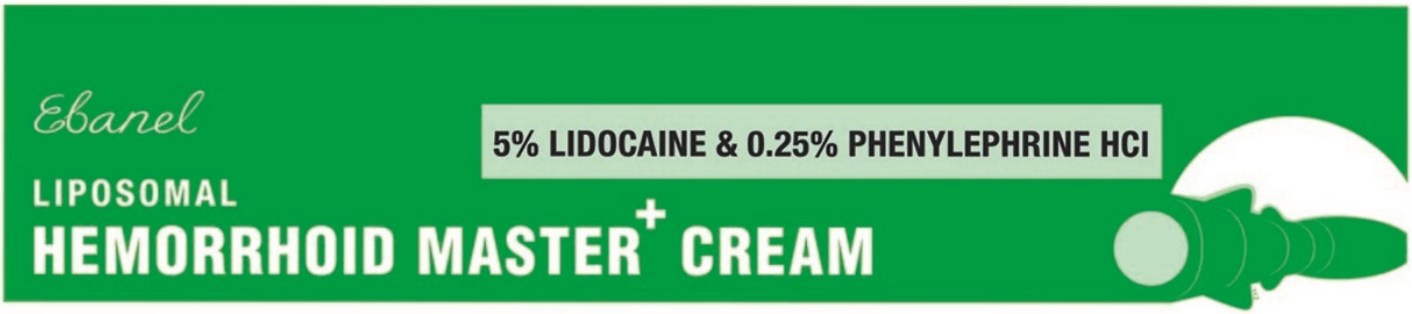
Other Information

- 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.

Inactive Ingredients

Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Alcohol, Aloe Barbadensis Leaf Juice, Argania Spinosa Kernel Oil, BHA, BHT, Boswellia Serrata Resin Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Caprylyl Glycol, Carbomer, Carthamus Tinctorius (Safflower) Seed Oil, Centella Asiatica Extract, Cetearyl Alcohol, Cetearyl Glucoside, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Cocos Nucifera (Coconut) Oil, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel) Water, Hexylene Glycol, Hydroxyethylcellulose, Isopropyl Myristate, Lavandula Angustifolia (Lavender) Oil, Myrtus Communis Oil, Panax Ginseng Root Extract, Panthenol, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Punica Granatum Fruit Extract, Pyridoxine HCl, Sodium Citrate, Sodium Metabisulfite, Stearic Acid, Tocopheryl Acetate, Triethanolamine, Water, Xanthan Gum, Zinc Oxide

Product label



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LIPOSOMAL HEMORRHOID MASTER

lidocaine , phenylephrine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63742-038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARGAN OIL (UNII: 4V59G5UW9X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CHAMOMILE (UNII: FGL3685T2X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MYRTLE LEAF OIL (UNII: 4ZP3Q1OY08)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
PANTHENOL (UNII: WV9CM0O67Z)	
PEG-100 STEARATE (UNII: YD01N1999R)	

PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ALCOHOL (UNII: 3K9958V90M)	
SAFFLOWER OIL (UNII: 65UEH262IS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63742-038-01	1 in 1 CARTON	08/28/2024	
1		45 g 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 Drug	M015	08/28/2024	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Establishment

Name	Address	ID/FEI	Business Operations
Clinical Resolution Laboratory, Inc.		825047942	manufacture(63742-038)

Revised: 9/2024 Clinical Resolution Laboratory, Inc.