

HEMORROHOID MASTER CREAM- lidocaine, phenylephrine hcl cream
Ebanel Laboratories, Inc.

Active Ingredients

Lidocaine 5.00%

Phenylephrine HCl 0.25%

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.

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.

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.

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.

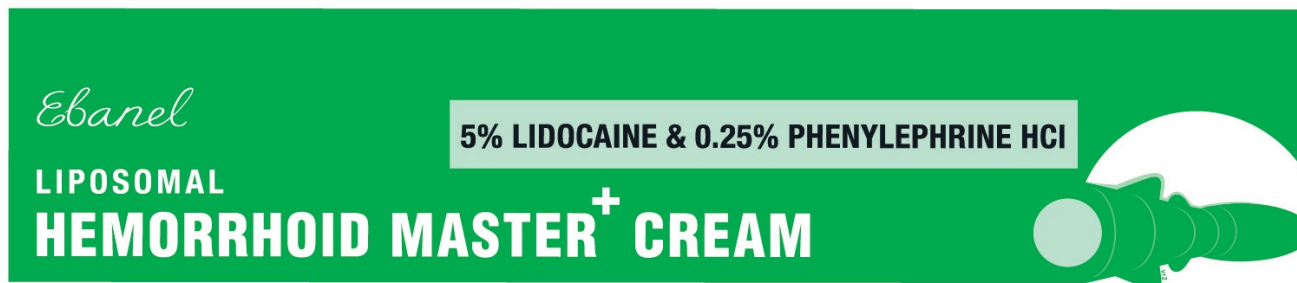
Inactive Ingredients

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

Purpose

Local Anesthetic

Vasoconstrictor



- For the Temporary Relief of **Pain, Burning, and Soreness**
- Temporarily Shrinks Hemorrhoidal Tissue
- Temporarily Reduces the Swelling associated with Irritation in Hemorrhoids

CHILD-RESISTANT PACKAGING

HEMORRHOIDAL CREAM

1.6 oz e 45 g

DRUG FACTS	
Active Ingredients	Purpose
Lidocaine 5.00%.....	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	

HEMORROHOID MASTER CREAM			
lidocaine, phenylephrine hcl cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72654-038
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 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)			
ALCOHOL (UNII: 3K9958V90M)			
CARBOMER (UNII: 0A5MM307FC)			
XANTHAN GUM (UNII: TTV12P4NEE)			
CHAMOMILE (UNII: FGL3685T2X)			
WITCH HAZEL (UNII: 101I4J0U34)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TRIETHANOLAMINE (UNII: 9O3K93S3TK)			
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)			
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)			
HEXYLENE GLYCOL (UNII: KEH0A3F75J)			
PEG-100 STEARATE (UNII: YD01N1999R)			
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL (UNII: ZBP1YXW0H8)			
CITRIC ACID (UNII: 2968PHW8QP)			
POMEGRANATE (UNII: 56687D1Z4D)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
BHT (UNII: 1P9D0Z171K)			
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
ARGANIA SPINOSA KERNEL OIL (UNII: 4V59G5UW9X)			
CETEARYL ALCOHOL (UNII: 2DMT128M1S)			
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)			
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)			
SODIUM METABISULFITE (UNII: 4VON5FNS3C)			
BHA (UNII: REK4960K2U)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
PANAX GINSENG ROOT (UNII: CUQ3A77YXI)			
PYRIDOXINE HCL (UNII: 68Y4CF58BV)			
HORSE CHESTNUT (UNII: 3C18L6RJAZ)			

ZINC OXIDE (UNII: SOI2LOH54Z)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PANTHENOL (UNII: WW9CM0O67Z)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL (UNII: 65UEH262IS)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAMELLIA SINENSIS VAR. ASSAMICA WHOLE (UNII: 6ZU7I0L9K2)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
HYDROXYETHYLCELLULOSE (UNII: T4V6TWG28D)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
MYRTUS COMMUNIS OIL (UNII: 4ZP3Q1OY08)	

Product Characteristics

Color	white (Yellowish offwhite)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72654-038-01	45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	06/06/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	06/06/2025	

Labeler - Ebanel Laboratories, Inc. (079352161)

Registrant - Clinical Resolution Laboratory, Inc. (825047942)

Establishment

Name	Address	ID/FEI	Business Operations
Clinical Resolution Laboratory, Inc.		825047942	manufacture(72654-038)