

**HEMORRHOID MASTER- lidocaine, phenylephrine ointment**  
**Ebanel Laboratories, Inc**

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**Hemorrhoid Master**

**DRUG FACTS**

**Active Ingredient**

Lidocaine 4.00%

Phenylephrine HCl 0.25%

**Purpose**

Analgesic (Pain Relief)

(Vasoconstrictor)

**Uses**

- Helps relieve the anorectal itching and discomfort in the perianal area.
- Temporarily reduces swelling associated with irritation in hemorrhoids and other anorectal disorders.
- Temporarily shrinks hemorrhoidal tissue.

**Warnings**

**For external and or intrarectal use only.**

**Stop use and ask a doctor**

- If condition worsens or does not improve within 7 days.
- in case of bleeding.
- if allergic reaction to product occurs. If the symptoms being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase.

**When using this product**

do not exceed the recommended daily dosage unless directed by 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.
- with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult doctor promptly.

## **Ask a doctor before use**

if you are

- presently taking a prescription drug for high blood pressure or depression.

## **Keep out of reach of children:**

If swallowed, seek medical help or contact a Poison Control Center immediately.

## ***Directions***

*Adults:* Apply to the affected area up to 3 times daily.

- Children under 12 years of age: consult a doctor.
- When practical, clean affected area with mild soap and warm water and rinse thoroughly. Gently dry (patting or blotting) with tissue or soft cloth before use.
- To use dispensing cap, attach it to tube, lubricate well, then gently 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.

## ***For Intrarectal Use:***

Attach applicator to tube. Lubricate well, then gently insert applicator into the rectum.

**For External use:** Do not put this product into the rectum using fingers or any mechanical device.

## ***Inactive Ingredients***

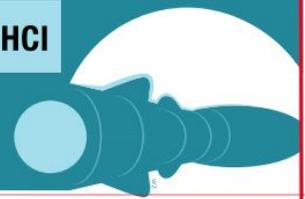
Aloe Barbadensis Leaf Juice, Ascorbic Acid, Ascorbyl Palmitate, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Cetearyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Cholecalciferol, Cholesterol, Diisopropyl Sebacate, Dimethyl Isosorbide, Dodecane, Ethoxydiglycol, Ethylhexylglycerin, Hexylene Glycol, Hydrocortisone, Isododecane, Isopropyl Myristate, Lecithin, Mentha Piperita (Peppermint) Oil, Microcrystalline Wax, Mineral Oil, Octyldodecanol, Panax Ginseng Root Extract, PEG-8 Dimethicone, Petrolatum, Phenoxyethanol, Phospholipids, Polyethylene, Polysorbate 80, Propylene Glycol, Punica Granatum Extract, Pyridoxine HCl, Retinyl Palmitate, Silica, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Zea Mays (Corn) Oil, Zinc Oxide.

## **Package Labeling:**

Ebanel

4% LIDOCAINE & 0.25% PHENYLEPHRINE HCl

LIPOSOMAL  
HEMORRHOID MASTER



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

HEMORRHOIDAL OINTMENT

Enhanced with inactive ingredients: Hydrocortisone, Vitamin B6, Aloe, Chamomile, Ginseng

1.6 oz e 45 g

**DRUG FACTS**

<b>Active Ingredients</b>		<b>Purpose</b>
Lidocaine 4.00%.....		Local Anesthetic
Phenylephrine HCl 0.25%.....		Vasoconstrictor
<b>Uses:</b> ■ 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.		
<b>Warnings:</b> 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.		
<b>Directions:</b> 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.		<b>For External Use:</b> Apply externally to the affected area up to 4 times daily.
<b>For Intrarectal Use:</b> Attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Apply to the affected area up to 4 times daily.		<b>Other Information:</b> ■ Keep away from direct sunlight or heat. ■ Store at room temperature 15°-30°C (59°-86°F). ■ 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.
<b>Inactive Ingredients:</b> Aloe Barbadosensis Leaf Juice, Ascorbic Acid, Ascorbyl Palmitate, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Cetearyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Cholecalciferol, Cholesterol, Diisopropyl Sebacate, Dimethyl Isosorbide, Dodecane, Ethoxydiglycol, Ethylhexylglycerin, Hexylene Glycol, Hydrocortisone, Isododecane, Isopropyl Myristate, Lecithin, Mentha Piperita (Peppermint) Oil, Microcrystalline Wax, Mineral Oil, Octyldecylol, Panax Ginseng Root Extract, PEG-8 Dimethicone, Petrolatum, Phenoxethanol, Phospholipids, Polyethylene, Polysorbate 80, Propylene Glycol, Punica Granatum Extract, Pyridoxine HCl, Retinyl Palmitate, Silica, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylsilane, Zea Mays (Corn) Oil, Zinc Oxide		

**HEMORRHOID MASTER**

lidocaine, phenylephrine ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72654-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g
PHENYLEPHRINE (UNII: 1WS297W6MV) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHAMOMILE (UNII: FGL3685T2X)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	

<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)
<b>DODECANE</b> (UNII: 11A386X1QH)
<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A18X02B)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ)
<b>ISODODECANE</b> (UNII: A8289P68Y2)
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)
<b>PEG-8 DIMETHICONE</b> (UNII: GIA7T764OD)
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>PUNICA GRANATUM ROOT BARK</b> (UNII: CLV24I3T1D)
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM PROPOXYHYDROXYPROPYL THIOSULFATE SILICA</b> (UNII: 208G222332)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>CORN</b> (UNII: 0N8672707O)
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72654-002-01	45 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/01/2019	

**Labeler** - Ebanel Laboratories, Inc (079352161)

