

HEMAWAY- lidocaine cream
Melaleuca, Inc.

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.

HemAway Maximum Strength Hemorrhoid Relief Cream

Uses

Temporarily relieves pain, itching and discomfort due to anorectal disorders.

Warnings

For External use only

Allergy alert: Certain persons can develop allergic reactions to ingredients in this product.

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.
- Adults and children 12 years and older: apply externally to the affected area up to 4 times a day.
- Children under 12 years of age: consult a doctor.

Other information

- To secure child-resistant cap: screw cap tightly. Then turn cap in opposite direction. If clicking sound is not heard, repeat procedure.
- Tamper-Evident: do not use if foil seal under cap is broken or missing.
- See crimp of tube for lot number and expiration date.

Inactive ingredients: Aloe Barbadensis Leaf Juice Extract, Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Triethanolamine, vitamin E Acetate, Vitis Vinifera (Grape) Skin Extract

Active Ingredients

Lidocaine 5%

Local anesthetic

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

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

Stop use and ask a Doctor if:

- Rectal bleeding occurs
- Conditions worsens or does not improve within 7 days
- Allergic reaction occurs
- Symptoms clear up and return in a few days
- Redness, irritation, swelling, pain or other symptoms begin or increase

Ask a Doctor or Pharmacist if you are: Presently taking a prescription drug for high blood pressure or depression.

If pregnant or breast feeding ask a health professional before use.

When using this product:

- Do not put this product into the rectum by using fingers or any mechanical device or applicator.
- Do not exceed the recommended daily dosage unless directed by a doctor.



Active Ingredients: Lidocaine 5%

Uses: Temporarily relieves pain, itching and discomfort due to anorectal disorders.

Allergy alert - Certain persons can develop allergic reactions to ingredients in this product.

Ask a doctor before use if you have heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urination due to enlargement of the prostate gland.

Stop use and ask a doctor if rectal bleeding occurs, condition worsens or does not improve within 7 days; an allergic reaction develops, symptoms clear up and return within a few days, redness, irritation, swelling, pain or other symptoms begin or increase.

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression. **If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

When using this product, do not put this product into the rectum by using fingers or any mechanical device or applicator. Do not exceed the recommended daily dosage unless directed by a doctor.

Relieves pain, burning, itching

- Contains Soothing Aloe, Vitamin E, and Grape Skin Extract
- Powerful Pain Relief

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.

Adults and children 12 years and older: apply externally to the affected area up to 4 times a day. Children under 12 years of age: consult a doctor.

Warning: For External Use Only

Net wt. 1oz. (30g)

To secure child-resistant cap: screw cap tightly. Then turn cap in opposite direction. If clicking sound is not heard, repeat procedure.

Inactive ingredients: Purified Water, Isopropyl Myristate, Carbomer, Hydrogenated Lecithin, Cholesterol, Benzyl Alcohol, Aloe Barbadensis Leaf Juice, Vitamin E Acetate, Polysorbate 80 Propylene Glycol, Triethanolamine, Vitis Vinifera (Grape) Skin Extract

TAMPER-EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OR MISSING.

See crimp of tube for lot number and expiration date

Distributed by: HemAway LLC
15 Bay 29th Street, 2nd Floor, Brooklyn, NY 11214

MADE IN USA

TB1-TC1



HEMAWAY

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-336
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	1.5 g in 30 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GRAPE (UNII: 6X543N684K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-336-01	1 in 1 BOX	08/04/2020	
1	NDC:54473-336-30	30 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 final	part346	08/04/2020	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		805617610	manufacture(54473-336)

Revised: 1/2023

Melaleuca, Inc.