

HEMAWAY - lidocaine and phenylephrine hcl 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.

Uses

Temporarily relieves pain, itching and discomfort due to anorectal disorders and temporarily shrinks hemorrhoidal tissue.

Warnings

For External use only

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
- 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
- Allergic reaction occurs
- 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

Directions

- Adults: when practical, cleanse the affected area with mild soap and warm water. 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 Barbadosis 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	Purpose
Lidocaine 5%.....	Local anesthetic
Phenylephrine HCl.....	Vasoconstrictor

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



HEMAWAY

lidocane and phenylephrine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-180
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 -	PHENYLEPHRINE	2.5 mg

UNII:1WS297W6MV)

HYDROCHLORIDE

in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
CARBOMER HOMO POLYMER 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:54473-180-01	1 in 1 BOX		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/13/2010	

Labeler - Melaleuca, Inc. (139760102)**Registrant** - Melaleuca, Inc. (139760102)**Establishment**

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		805617610	manufacture(54473-180)

Revised: 12/2010

Melaleuca, Inc.