

HEMORRHOIDAL RELIEF CREAM- lidocane and phenylephrine hcl cream

CVS Pharmacy, 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.

CVS Health Maximum Strength Hemorrhoidal Relief Cream

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

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 Barbadosensis 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.

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.

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 doct

J60201A1

APPROVED ARTWORK
FG SKU: 04-102099403
Box SKU: 04-502199403
QA Int/Date: BB 09/13/2016

CVS Health.
Hemorrhoidal Relief Cream

Compare to RectiCare®
NDC 59779-279-53

MAXIMUM STRENGTH
Hemorrhoidal Relief Cream
LIDOCAINE 5% - Local anesthetic
PHENYLEPHRINE HCl .25% - Vasoconstrictor

For numbing relief

- Relieves pain, burning, itching & reduces swelling
- Contains soothing aloe, Vitamin E & grape skin extract
- Shrinks hemorrhoidal tissue

NET WT 30g

#998565
0 50428 38473 2

GLUE-NC

Drug Facts

Active Ingredients **Purpose**
Lidocaine 5% Local anesthetic
Phenylephrine HCl 0.25% Vasoconstrictor

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
Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.
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.
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
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.

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.

Directions (continued)
■ 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.
■ see crimp of tube for lot number and expiration date.

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 FOL SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients: Aloe Barbadensis Leaf Juice Extract, Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Hydroxyethyl Cellulose, Propylene Glycol, Purified Water, Triethyl Citrate, Vitamin E Acetate, Zinc Vitraria (ZnO) Skin Extract.

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
© 2015 CVS/pharmacy
CVS.com® 1-800-SHOP CVS
Made in the U.S.A.
V-31822

*This product is not manufactured or distributed by Fendale Healthcare®, Inc., owner of the registered trademark Recticare®.

CVS Quality
Money Back Guarantee

BX-TC1

PLEASE RECYCLE

JOB INFORMATION		PROOF		NAME: NCD_59779_279_53_CTVL		SUGGESTED ITEMS TO REVIEW		PLEASE NOTE:		
	PROOF 13465 JUPITER ROAD DALLAS, TX 75238	NAME: NCD_59779_279_53_CTVL	DATE: 08/11/16	Color Placement	PLEASE NOTE: PANTONE® or special metallic inks used in this proof may not match the PANTONE® solid color standards. Use the current PANTONE® swatch guide for the most accurate color representation.					
		DIE_TRIM SIZE:	TIME: 5:27 PM	Copy (Spelling, Fonts)						
		HEIGHT 6.5781	WIDTH 7.6563	Barcode						
USED COLORS:		zDIE	CYAN	MAGENTA	YELLOW	BLACK				
					PMS 186 C	GLOSS UV				

HEMORRHOIDAL RELIEF CREAM
lidocane and phenylephrine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-984	
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	
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:69842-984-01	1 in 1 BOX	05/01/2017	
1	NDC:69842-984-02	28 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	12/13/2010		

Labeler - CVS Pharmacy, Inc (062312574)

Registrant - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		805617610	manufacture(69842-984)

