# BUNNIES BUM SOOTHING HEMORRHOIDAL- glycerin, lidocaine, petrolatum, phenylephrine hcl cream FloCal Distributors LLC

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#### **Bunnies Bum Creme Soothing Hemorrhoidal**

Glycerin 14.4%, Lidocaine 5%, Petrolatum 15%, Phenylephrine HCl 0.25%

Glycerin-Protectant

Lidocaine-Local anesthetic

Petrolatum-Protectant

Phenylephrine HCI Vasoconstrictor

- For the temporary relief of pain, soreness, and burning
- Helps relieve the local itching and discomfort associated with hemorrhoids
- Temporarily shrinks hemorrhoidal tissue
- Temporarily provides a costing for the relief of anorectal discomforts
- Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

#### For external use only.

#### 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

- avoid contact with eyes
- do not exceed recommended dosage unless directed by a doctor
- do not put this into the rectum by using fingers or any mechanical device or applicator

## Stop use and ask a doctor if

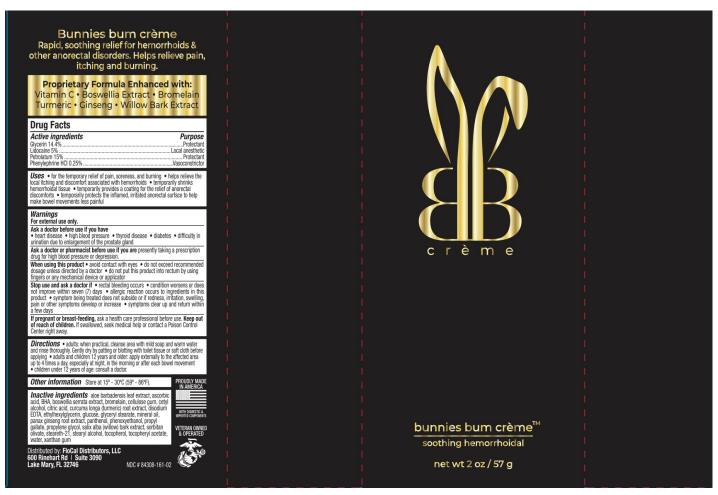
- rectal bleeding occurs
- condition worsens or does not improve within 7 days
- allergic reaction occurs to ingredients in this product
- symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase
- symptoms clear up and return within a few days

Ask a health professional before use.

If swallowed, get medical help or contact a Poison Control Center right away.

- Adults: when practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 4 times a day, especially at night, in the morning, or after each bowel movement.
- Children under 12 years of age: consult a doctor.

Aloe barbadensis leaf extract, ascorbic acid, BHT, boswellia serrata extract, bromelain, cellulose gum, cetyl alcohol, citric acid, curcuma long (turmeric) root extract, disodium EDTA, ethylhexylglycerin, glucose, glyceryl stearate, mineral oil, panax ginseng root extract, panthenol, phenoxyethanol, propyl gallate, propylene glycol, salix alba (willow) bark extract, sorbitan olivate, steareth-21, stearyl alcohol, tocopherol, tocopheryl acetate, water, xanthan gum.



#### **BUNNIES BUM SOOTHING HEMORRHOIDAL**

glycerin, lidocaine, petrolatum, phenylephrine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84308-161
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	<b>Basis of Strength</b>	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients	Strongth
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MINERAL OIL (UNII: T5L8T28FGP)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PANTHENOL (UNII: WV9CM0067Z)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
TOCOPHEROL (UNII: ROZB2556P8)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TURMERIC (UNII: 856YO1Z64F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARETH-21 (UNII: 53J3F32P58)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BROMELAINS (UNII: U182GP2CF3)	
SALIX ALBA BARK (UNII: 205MXS71H7)	

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
3	NDC:84308-161- 02	57 g in 1 TUBE; Type 0: Not a Combination Product	07/08/2024	

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M015	07/08/2024	

## **Labeler -** FloCal Distributors LLC (128775688)

# Registrant - Derma Care Research Labs LLC (116817470)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Derma Care Research Labs LLC		116817470	manufacture(84308-161)	

Revised: 7/2024 FloCal Distributors LLC