BOTTOMS UP HEALTH- lidocaine,glycerin,calamine,witch hazel cream
CENTURA PHARMACEUTICALS 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.

ACTIVE INGREDIENTS

Calamine 15%

Glycerin 35%

Lidocaine 5%

Witch Hazel 10%

PURPOSE

Protectant, Protectant, Anesthetic, Protectant

USES

Helps relieve the pain, burning, soreness and itching associated with inflamed hemorrhoidal tissue and other anorectal disorders.

Temporarily protects inflamed and irritated anorectal surface to help make bowel movements less.

WARNINGS

For external use only

STOP USE AND ASK A DOCTOR IF

■ the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase ■ condition worsens or does not improve within 7 days

ALLERGY ALERT

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

OTHER WARNINGS

Do not exceed the recommended dose unless directed by a doctor.

In case of bleeding, consult a doctor promptly.

Do not put this product into the rectum by using fingers or any mechanical device or applicator.

KEEP OUT OF REACH OF CHILDREN

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

IF PREGNANT OR BREAST FEEDING

Ask a health professional before use.

DIRECTIONS

Adults and children over 12 years old ■ Apply externally to affected area up to 6 times a day or after each bowel movement

■ Clean affected area with mild soap and warm water, rinse thoroughly and gently dry by patting or blotting with toilet tissue or a soft cloth before using this product.

■ Children under 12 years of age: consult a doctor.

OTHER INFORMATION

Store at room temperature and away from direct sunlight.

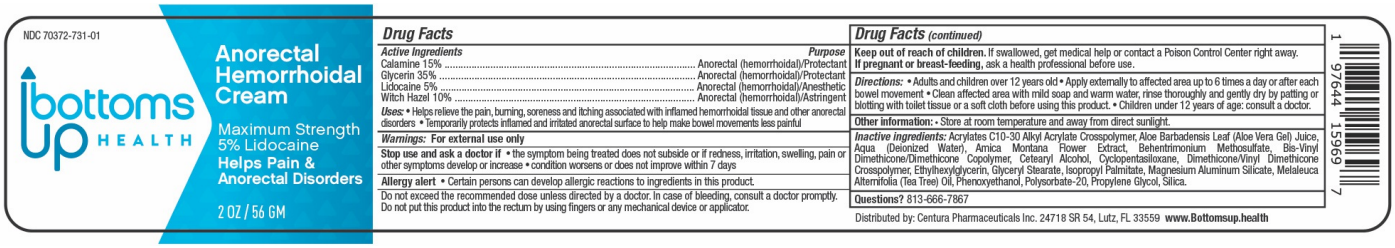
INACTIVE INGREDIENTS

Acrylates C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Amica Montana Flower Extract, Behentrimonium Methosulfate, Bis-Vinyl Dimethicone/Dimethicone Copolymer, Cetearyl Alcohol, Cyclopentasiloxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Ethylhexylglycerin, Glyceryl Stearate, Isopropyl Palmitate, Magnesium Aluminum Silicate, Melaleuca Alternifolia (Tea Tree) Oil, Phenoxyethanol, Polysorbate-20, Propylene Glycol, Silica.

QUESTIONS

813-666-7867

PACKAGE LABELING



BOTTOMS UP HEALTH

lidocaine,glycerin,calamine,witch hazel cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70372-731
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	35 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 g
WITCH HAZEL (UNII: 101I4J0U34) (WITCH HAZEL - UNII:101I4J0U34)	WITCH HAZEL	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TEA TREE OIL (UNII: VIF565UC2G)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70372-731-01	56 g in 1 JAR; Type 0: Not a Combination Product	05/27/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	05/27/2023	

Labeler - CENTURA PHARMACEUTICALS INC (084921637)

Registrant - CENTURA PHARMACEUTICALS INC (084921637)

Revised: 5/2023 CENTURA PHARMACEUTICALS INC