# COMFORT CANDY HEMORRHOIDAL- lidocaine, phenylephrine hydrochloride gel BOWLER ESTHETICS, INC

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# **Comfort Candy Hemorrhoidal Gel**

# **Drug Facts**

# **Active Ingredients**

Lidocaine 5.00 % Phenylephrine Hcl 0.25%

# **Purpose**

Anorectal (hemorrhoidal)
Anorectal (vasoconstrictor)

#### Uses

• For the temporary relief of pain, irritation, or burning.

# Warnings:

# For external use only

#### Do not

- exceed the recommended daily dosage unless directed by a doctor.
- put this product into the rectum by using your fingers or any mechanical device or applicator.
- use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate glad unless directed by a doctor.

# When using this product

- If the condition worsens or does not improve within 7 days, consult a doctor.
- In case of bleeding, consult a doctor promptly.

# 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.

# Ask a doctor or pharmacist before use if you are

• presently taking a prescription drug for high blood pressure or depression.

# Allergy alert

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

#### 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:

- When practical, cleanse the affected area with mild soap and warm water and rinse by patting or blotting with an appropriate cleansing pad.
- Gently dry by patting or blotting with toilet tissue or soft cloth before application of this product.
- Children under 12 years of age: consult a doctor.

#### Other information:

Protect the product in this container from excessive heat and direct sun.

# Inactive ingredients:

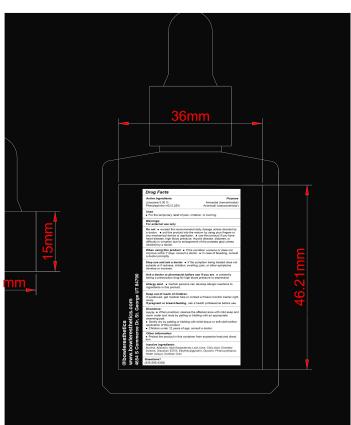
Alcohol, Allantoin, Aloe Barbadensis Leaf Juice, Citric Acid, Dimethyl Sulfone, Disodium EDTA, Ethylhexylglycerin, Glycerin, Phenoxyethanol, Water (Aqua), Xanthan Gum

#### Questions?

(435-295-4328)

# **Package Labeling:**







# **COMFORT CANDY HEMORRHOIDAL**

lidocaine, phenylephrine hydrochloride gel

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Prod	UCT	ıntorr	nation

Product Type HUMAN OTC DRUG Item Code (Soi	rce) NDC:85956-624
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**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 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
ALLANTOIN (UNII: 344S277G0Z)		
ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERIN (UNII: PDC6A3C0OX)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
WATER (UNII: 059QF0KO0R)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> 0	NDC:85956-624- 00	1 in 1 BOX	06/20/2025	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	06/20/2025	

# Registrant - Pure Source, LLC (080354456)

Revised: 7/2025 BOWLER ESTHETICS, INC