

## **HEMORRHOIDAL RELIEF CREAM- lidocaine cream**

### **Shield Line LLC**

*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.*

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## **Hemorrhoidal Relief Cream**

### ***Drug Facts***

#### ***Active ingredients***

Lidocaine USP 4%

Phenylephrine HCL USP 0.25%

#### ***Purpose***

Lidocaine USP 4%-----Local Anesthetic

Phenylephrine HCL USP 0.25%--Vasoconstrictor

#### ***Uses***

- Helps relieve the anorectal symptoms associated with hemorrhoids (pain, soreness, burning)
- Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders

### ***WARNINGS***

#### **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**

- do not exceed recommended daily usage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator

#### **Stop use and ask a doctor if:**

- bleeding occurs

- condition worsens or does not improve within 7 days
- an allergic reaction develops
- if symptoms being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

### **If pregnant or breast-feeding**

ask a healthcare professional before use

### **Keep out of reach of children:**

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

### ***Directions***

- **adults:** when possible, clean affected area with mild soap or warm water, rinse thoroughly, and then gently dry (patting or blotting) with tissue or soft cloth before use
- to use dispensing cap, attach it to the tube, lubricate well, then gently insert part way into anus and squeeze tube to deliver medication. Thoroughly cleanse dispensing cap after use with mild soap and warm water and rinse thoroughly
- apply to affected area upto 4 times daily, especially at night, when waking up and after each bowel movement

**Children** under 12 years of age: ask a doctor

### ***Other information***

- store at 59 to 77 F to avoid melting

### ***Inactive ingredients***

.Alpha.-Tocopherol Acetate, Aloe Vera Leaf, Asian Ginseng, Calendula officinalis Flower, Chamomile, Chlorocresol, Cholecalciferol, Coconut Oil, Corn Oil, Dimethicone, Fragrance, Hyaluronate Sodium, Hydrocortisone, Lysine Hydrochloride, menthol, Mineral Oil, Petrolatum, Propylene Glycol, Pyridoxine Hydrochloride, Sunflower Oil, Tricaprilin, Vitamin A Palmitate, yellow Wax, Zinc Oxide

### **Principal Display & Drug Fact Panel**



## Hemorrhoidal Relief Cream

**WITH APPLICATOR**

- Advance relief formula
- Helps to relieve the discomforts of hemorrhoids

Net Wt.  
1 oz (28.3g)

NDC: 52410-3077-5





Reorder No:  
MPR-30775



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<b>Drug Facts</b>		<b>WARNINGS</b> For external use only	
<b>Active ingredients</b>	<b>Purpose</b>	<b>Ask a doctor before use if you have</b>	
Lidocaine USP 4% Phenylephrine HCl USP 0.25%	Local Anesthetic Vasoconstrictor	<ul style="list-style-type: none"> <li>• heart disease • high blood pressure • thyroid disease • diabetes</li> <li>• difficulty in urination due to enlargement of the prostate gland</li> </ul>	
<b>Uses</b>		<b>Ask a doctor or pharmacist before use if you are</b> presently taking a prescription drug for high blood pressure or depression.	
<ul style="list-style-type: none"> <li>• Helps relieve the anorectal symptoms associated with hemorrhoids (pain, soreness, burning)</li> <li>• Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders</li> </ul>		<b>When using this product</b>	
		<ul style="list-style-type: none"> <li>• do not exceed recommended daily dosage unless directed by a doctor • do not put this product into the rectum by using fingers or any mechanical device for applicator</li> </ul>	
<b>Stop use and ask a doctor if:</b>		<b>Other information</b>	
<ul style="list-style-type: none"> <li>• bleeding occurs • condition worsens or does not improve within 7 days</li> <li>• an allergic reaction develops • if the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase</li> </ul>		<ul style="list-style-type: none"> <li>• Store at 59° to 77° F to avoid melting</li> </ul>	
<b>If pregnant or breast-feeding,</b> ask a health care professional before use.		<b>Inactive ingredients</b>	
<b>Keep out of reach of children:</b> If swallowed, seek medical help or contact a Poison Control Center right away		Alpha-Tocopherol Acetate, Aloe Vera Leaf, Asian Ginseng, Calendula Officinalis Flower, Chamomile, Chlorocresol, Cholecalciferol, Coconut Oil, Corn Oil, Dineethicone, Fragrance, Hyaluronic Acid, Hydrocortisone, Lysine Hydrochloride, Menthol, Mineral Oil, Petrolatum, Propylene Glycol, Pyridoxine Hydrochloride, Sunflower Oil, Tricaprilin, Vitamin A Palmitate, Yellow Wax, Zinc Oxide	
<b>Directions</b>		<b>Manufactured for:</b>	
<ul style="list-style-type: none"> <li>• <b>adults:</b> when possible, clean affected area with mild soap or warm water, rinse thoroughly, and then gently dry (patting or blotting) with tissue or soft cloth before use</li> <li>• to use dispensing cap, attach it to the tube, lubricate well, then gently insert part way into anus and squeeze tube to deliver medication. Thoroughly cleanse dispensing cap after use with mild soap and warm water and rinse thoroughly</li> <li>• apply externally to the affected area up to 4 times daily, especially at night, when waking up and after each bowel movement</li> <li>• <b>children</b> under 12 years of age: ask a doctor</li> </ul>		Shield Line LLC, Hackensack NJ 07601 USA Toll free: 800-277-6533 www.shieldline.com Made in India	
		 3 52410 30775 1	

LOT NO.  
 MFG DATE  
 EXP DATE

## HEMORRHOIDAL RELIEF CREAM

lidocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52410-3077
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	

<b>CHLOROCRESOL</b> (UNII: 36W53O7109)
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41)
<b>CORN OIL</b> (UNII: 8470G57WFM)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>LYSINE HYDROCHLORIDE</b> (UNII: JNJ23Q2COM)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ)
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>TRICAPRILIN</b> (UNII: 6P92858988)
<b>MENTHOL</b> (UNII: L7T10EIP3A)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)

<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:52410-3077-5	28.3 g in 1 TUBE; Type 0: Not a Combination Product	03/04/2021	

<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part346	03/04/2021		

**Labeler** - Shield Line LLC (078518916)