

**WARRIOR RECTAL CARE- lidocaine 4%, phenylephrine hydrochloride
0.25% ointment**

Derma Care Research Labs

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.

Warrior Rectal Care

Lidocaine 4%, Phenylephrine HCl 0.25%

Analgesic (pain relief), Vasoconstrictor

Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.

For external and/or intrarectal use only.

When using this product do not exceed recommended daily dosage unless directed by a doctor.

Do not use this product if you have difficulty in urination due to enlargement of the prostate gland. Diabetes, heart disease, high blood pressure, thyroid disease. Presently taking a prescription for high blood pressure or depression.

Stop use and ask a doctor if condition worsens or does not improve within seven days, bleeding occurs. Introduction of applicator into the rectum causes additional pain.

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

Children under 12 years of age consult your pediatrician.

Adults: apply to affected area up to 4 times daily.

Clean affected area with mild soap and warm water, rinse thoroughly, and then gently dry (patting or blotting) with tissue or soft cloth before use.

FOR INTRARECTAL USE: attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Thoroughly cleanse applicator after each use and replace cover.

Aloe Barbadosensis Leaf Extract, Calendula Officinalis Flower Extract, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Chamomilla Recutita (Matricaria) Flower Extract, Glycerin, Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Lysine HCl, Mineral Oil,

Olea Europaea (Olive) Fruit Oil, Petrolatum, Punica Granatum Extract, Retinyl Palmitate, Stearic Acid, Tocopheryl Acetate, Water

Ask a health professional before use.

<p>Drug Facts</p> <p>Active ingredients</p> <p>Lidocaine 4%Local anesthetic Phenylephrine Hydrochloride 0.25%Vasoconstrictor</p> <p>Purpose</p>	<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are • presently taking a prescription drug for high blood pressure or depression</p> <p>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 • introduction of applicator into the rectum causes additional pain • symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase</p> <p>If pregnant or breastfeeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
<p>Uses Helps relieve the pain, itching and burning associated with hemorrhoids and other anorectal disorders</p>	
<p>Warnings</p> <p>For external and/or intrarectal use only</p> <p>When using this product • do not exceed recommended dosage unless directed by a doctor</p> <p>Do not use this product if you have • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.</p>	

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R01242023

<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 6 times a day. • FOR INTRARECTAL USE: Attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Thoroughly cleanse applicator after each use and replace cover. • Children under 12 years of age: consult a doctor. 	<p>Drug Facts (continued)</p> <p>Questions? (888) 269-3983 Ext 701</p> <p>Inactive ingredients Aloe Barbadensis Leaf Extract, Calendula Officinalis Flower Extract, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Chamomilla Recutita (Matricaria) Flower Extract, Glycerin, Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Lysine HCl, Mineral Oil, Olea Europaea (Olive) Fruit Oil, Petrolatum, Punica Granatum Extract, Retinyl Palmitate, Stearic Acid, Tocopheryl Acetate, Water</p>
<p>Other information Store at 15°-30° C (59°-86° F)</p>	<p>MANUFACTURED FOR UNITED SPIRIT OF AMERICA, INC. PEACHTREE CITY, GA 30269 DAPA SP0200-11-H0034 CARDINAL HEALTH SUP 117301, OWENS & MINOR VENDOR 6516</p>

Net Wt 1.0 OZ (28 g)

FAST ACTING

A-RELIEF

RECTAL CARE CREAM

LIDOCAINE 4% & PHENYLEPHRINE
HYDROCHLORIDE 0.25%

Rapid Pain Relief for Hemorrhoids
& Other Anorectal Disorders

Quickly Relieves Pain,
Itching, & Burning



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WARRIOR RECTAL CARE			
lidocaine 4%, phenylephrine hydrochloride 0.25% ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE (UNII: V5VD430YW9)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
MINERAL OIL (UNII: T5L8T28FGP)	
MATRICARIA CHAMOMILLA LEAF (UNII: 6I9LN466F0)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PETROLATUM (UNII: 4T6H12BN9U)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-071-01	1 in 1 CARTON	01/23/2023	
1		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	01/23/2023	

Labeler - Derma Care Research Labs (116817470)**Registrant** - Derma Care Research Labs (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-071)

Revised: 5/2023

Derma Care Research Labs