

DCH RAPID RELIEF HEMORRHOIDAL- lidocaine 5%, phenylephrine hydrochloride 0.25% spray
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.

DCH Rapid Relief Hemorrhoidal Spray

Lidocaine 5%, Phenylephrine HCl 0.25%,

Topical Anesthetic, Vasoconstrictor

Helps relieve the local itching and discomfort associated with anorectal disorders or inflammation.

For external use only.

Flammable--do not use while smoking or near heat or flame.

When using this product avoid contact with eyes, contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120F, do not exceed recommended daily dosage unless directed by a doctor, do not put this product in the rectum by using fingers or any mechanical device or applicator.

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, presently taking a prescription for high blood pressure or depression.

Stop use and ask a doctor if rectal bleeding occurs, the condition worsens or symptoms 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.

Ask a healthcare or professional before use.

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

When practical, cleanse the affected area with mild soap and warm water, rinse thoroughly, and gently pat dry. Spray the affected area, wash hands after applying.

Adults and children 12 years and older: apply externally to the affected area up to 6 times a day. **Children under 12 years of age:** consult a doctor.

Alcohol, Aloe Barbadosis Leaf Extract, Citric Acid, Disodium EDTA, Glycerin, Malic Acid, Menthol, Propyl Gallate, Propylene Glycol, Sodium Benzoate, Water.



DCH LABS

Drug Facts

Active ingredients

Lidocaine 5% Topical anesthetic
Phenylephrine HCl 0.25% Vasoconstrictor

Purpose

Use Helps relieve the local itching and discomfort associated with anorectal disorders or inflammation

Warnings

For external use only

Flammable - do not use while smoking or near heat or flame

When using this product • avoid contact with eyes • do not exceed recommended dosage 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 • 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

If pregnant or breastfeeding, ask a health professional before use
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions • when practical, cleanse the affected area with mild soap and warm water • rinse thoroughly and gently pat dry • spray affected area • wash hands after applying • **adults and children 12 years and older:** apply externally to the affected area up to 6 times a day • **children under 12 years of age:** consult a doctor

Other information • store at 15°-30° C (59°-86° F) • contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F

Inactive ingredients alcohol denat., aloe barbadensis leaf extract, citric acid, disodium EDTA, glycerin, malic acid, menthol, propyl gallate, propylene glycol, sodium benzoate, water

* This product is not manufactured or distributed by Pfizer, owner of the registered trademark Preparation H ®.



Manufactured by:
DermaCare Research Labs, LLC
440 Fantress Blvd., Daytona Beach, FL 32114



Rapid Relief Hemorrhoidal Spray

Maximum Strength

Lidocaine 5%
Phenylephrine HCl 0.25%

Rapid Numbing Relief
of Pain, Itching & Burning

Reduces Swelling & Provides
a Soothing Protective Layer

Sprays at Any Angle

* Compare to active ingredients in Preparation H Rapid Relief®

NET WT 5 OZ (142 g)

DCH RAPID RELIEF HEMORRHOIDAL

lidocaine 5%, phenylephrine hydrochloride 0.25% spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72839-263 |
| 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 |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE | 0.25 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE (UNII: V5VD430YW9) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYL GALLATE (UNII: 8D4SNN7V92) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MALIC ACID (UNII: 817L1N4CKP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72839-263-05 | 142 g in 1 CAN; Type 0: Not a Combination Product | 02/24/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346 | 02/24/2023 | |

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(72839-263) |

Revised: 7/2023

Derma Care Research Labs