

**HEMORRHOID AND FISSURE DR. BUTLER- lidocaine 4.00, phenylephrine hydrochloride
0.25 ointment**

Beyond Health P.A.

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.

Analgesic (pain relief), Vasoconstrictor

Helps relieve the anorectal symptoms associated with hemorrhoids (pain, soreness, burning, itching). Temporarily reduces the swelling associated with irritated hemorrhoidal tissue 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.

Ask a doctor before use if you have allergies to any of the components of this product. 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 pregnant or breastfeeding, ask a health professional before use.

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 3 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.

To use dispensing cap, attach it to 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.

Bio-Enhanced with Herbs, Minerals, and Amino Acids

✓ **Proctologist Developed**

✓ **Protects & Soothes the Irritated Tissue**



MAXIMUM STRENGTH HEMORRHOID & FISSURE OINTMENT

Helps to Instantly Relieve Pain, Burning, Itching and Swelling

www.DoctorButlers.com

"Leave the Pain Behind"

NET WT 1 OZ (28g)

| | |
|--|---|
| <p>Drug Facts</p> | <p>Drug Facts (continued)</p> |
| <p>Active Ingredients</p> <p>Lidocaine USP 4.00%.....Analgesic (pain relief) Phenylephrine HCl 0.25%.....(Vasoconstrictor)</p> | <p>When using this product</p> <ul style="list-style-type: none"> Do not exceed recommended daily dosage unless directed by a doctor. |
| <p>Uses</p> <ul style="list-style-type: none"> Helps relieve the anorectal symptoms associated with hemorrhoids (pain, soreness, burning, itching). Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders. | <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> Allergies to any of the components of this product. 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. |
| <p>Warnings</p> <p>For external and/or intrarectal use only. →</p> | <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> Condition worsens or does not improve within seven (7) days. Bleeding occurs. Introduction of applicator into the rectum causes additional pain. <p>If pregnant or breast-feeding, ask a health care professional before use. ↓</p> |

| | |
|--|---|
| <p>Drug Facts (continued)</p> | <p>Drug Facts (continued)</p> |
| <p>Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center right away.</p> | <p>Inactive ingredients Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Algae Extract, Aloe Barbadosis Leaf Extract, Ascorbic Acid, Calendula Officinalis Flower Extract, Capric/Caprylic Triglyceride, Centella Asiatica Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cholecalciferol, Helianthus Annuus (Sunflower) Seed Oil, Hydrocortisone, Lysine HCl, Methylparaben, Mineral Oil, Octyldodecanol, Panax Ginseng Root Extract, PEG-8</p> |
| <p>Directions</p> <ul style="list-style-type: none"> Children under 12 years of age consult your pediatrician. Adults: apply to the affected area up to 3 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. To use dispensing cap, attach it to 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. | <p>Dimethicone, Petrolatum, Propylene Glycol, Propylparaben, Punica Granatum Extract, Pyridoxine HCl, Retinyl Palmitate, Silica, Sodium Hyaluronate, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylsilane, Water, Zea Mays (Corn) Oil, Zinc Oxide.</p> |
| <p>Other information</p> <ul style="list-style-type: none"> Store at 59° to 77°F to avoid melting. → | |

Distributed by:
Beyond Health P.A.
Tequesta, FL 33469
Phone: (561) 935-9698

www.DoctorButlers.com
Questions? Email us at
support@DoctorButlers.com

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Package Not Child-Resistant

"Leave the Pain Behind"

NET WT 1 OZ (28g)

Drug Facts

Active ingredients

Lidocaine 4.00%.....Analgesic (pain relief)
Phenylephrine Hydrochloride 0.25%.....(Vasoconstrictor)

Purpose

Uses

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

Drug Facts (continued)

Warnings

For external and/or intrarectal use only.

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

Ask a doctor before use if you have:

- Allergies to any of the components of this product.
- 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.

Drug Facts (continued)

Stop use and ask a doctor if:

- Condition worsens or does not improve within seven (7) days.
- Bleeding occurs.
- Introduction of applicator into the rectum causes additional pain.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center right away.

Directions

- Children under 12 years of age consult your pediatrician.
- Adults: apply to the affected area up to 3 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.
- To use dispensing cap, attach it to 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.

Drug Facts (continued)

Other information

- Store at 59° to 86°F to avoid melting.

Inactive ingredients Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Algae Extract, Aloe Barbadosensis Leaf Extract, Ascorbic Acid, Calendula Officinalis Extract, Capric/Caprylic Triglyceride, Centella Asiatica Extract, Chamomilla Recutita (Matricaria) Flower Oil, Cholecalciferol, Helianthus Annuus (Sunflower) Seed Oil, Hydrocortisone, Lysine HCl, Methylparaben, Mineral Oil, Octyldodecanol, Olea Europaea (Olive) Fruit Oil, Panax Ginseng Root Extract, PEG-8 Dimethicone, Petrolatum, Propylene Glycol, Propylparaben, Punica Granatum Extract, Pyridoxine HCl, Retinyl Palmitate, Silica, Sodium Hyaluronate, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylsilane, Water, Zea Mays (Corn) Oil, Zinc Oxide.

Distributed by:
Beyond Health PA
Daytona Beach, FL 32117
Phone: (561) 935-9698
Questions? Email us at
ROBCUT2@YAHOO.COM



HEMORRHOID AND FISSURE DR. BUTLER

lidocaine 4.00, phenylephrine hydrochloride 0.25 ointment

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70942-023 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| HORSE CHESTNUT (UNII: 3C18L6RJAZ) | |
| ALOE (UNII: V5VD430YW9) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| TRICAPRYLIN (UNII: 6P92858988) | |
| CENTELLA ASIATICA (UNII: 7M867G6T1U) | |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) | |
| SUNFLOWER OIL (UNII: 3W1JG795Y) | |
| HYDROCORTISONE (UNII: WI4X0X7BPJ) | |
| LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| OCTYLDODECANOL (UNII: 461N1O614Y) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| ASIAN GINSENG (UNII: CUQ3A77YXI) | |
| PEG-8 DIMETHICONE (UNII: GIA7T764OD) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D) | |
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| SODIUM PROPOXYHYDROXYPROPYL THIOSULFATE SILICA (UNII: 208G222332) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E) | |
| WATER (UNII: 059QF0KO0R) | |
| CORN OIL (UNII: 8470G57WFM) | |
| ZINC OXIDE (UNII: SOI2LOH54Z) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70942-023-01 | 1 in 1 CARTON | 08/28/2007 | |
| 1 | | 28 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:70942-023-11 | 1 in 1 CARTON | 08/27/2019 | |
| 2 | | 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 | 08/28/2007 | |

Labeler - Beyond Health P.A. (026781064)

Registrant - Derma Care Research Labs (116817470)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Derma Care Research Labs | | 116817470 | manufacture(70942-023) |

Revised: 7/2020

Beyond Health P.A.