

**DOCTOR BUTLERS HEMORRHOID AND FISSURE EXTERNAL PAIN FORMULA-
lidocaine 5% 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.

Doctor Butler's Hemorrhoid & Fissure Ointment External Pain Formula

Lidocaine 5.0%

Local Anesthetic

Uses

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

For external use only.

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, or symptoms clear up and return within a few days.

If pregnant or breastfeeding, ask a professional before use.

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

- When practical, cleanse the area with mild soap and warm water. Rinse thoroughly and gently pat dry.
- 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.

Aesculus Hippocastanum (Horse Chestnut) Extract, Benzyl Alcohol, Calendula Officinalis Flower Extract, Calendula Officinalis flower Extract, Carbomer, Carya Ovata Bark Extract, Centella Asiatica Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cholesterol, Curcuma Longa (Turmeric) Root Extract, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Helichrysum Italicum Extract, Hydrogenated Lecithin, Isopropyl Myristate, Lavandula Angustifolia (Lavender) Flower Extract, Melaleuca Alternifolia (Tea Tree) Leaf Extract, Olea Europaea (Olive) Leaf Extract, Panax Ginseng Root Extract, Polysorbate 80, Propylene Glycol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hyaluronate, Tocopheryl Acetate, Triethanolamine, Water.

Proctologist Developed



Medicated Treatment

- Powerful Medicine Contains **Lidocaine**
- Paraben-Free
- Bio-Enhanced with Herbal & Plant Extracts



"Leave the Pain Behind"™

EXTERNAL PAIN FORMULA

HEMORRHOID & FISSURE OINTMENT

Instant Relief from Pain

Package Not Child-Resistant

NET WT 1 OZ (28g)

Drug Facts (continued)

Other information

- store at 15°-30°C (59° to 86° F)

Inactive ingredients

aesculus hippocastanum (horse chestnut) extract, benzyl alcohol, calendula officinalis flower extract, carbomer, carya ovata bark extract, centella asiatica extract, chamomilla recutita (matricaria) flower extract, cholesterol, curcuma longa (turmeric) root extract, hamamelis virginiana (witch hazel) leaf extract, helichrysum italicum extract, hydrogenated lecithin, isopropyl myristate, lavandula angustifolia (lavender) flower extract, melaleuca

Drug Facts - Inactive Ingredients (continued)

alternifolia (tea tree) leaf extract, olea europaea (olive) leaf extract, panax ginseng root extract, polysorbate 80, propylene glycol, rosmarinus officinalis (rosemary) leaf extract, sodium hyaluronate, tocopheryl acetate, triethanolamine, water



X0031VII05

Pain Relief Formula
New

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

www.DoctorButlers.com

Made in the U.S.A.
Cruelty Free - No Animal Testing



Questions? Email us at
support@DoctorButlers.com

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EXTERNAL PAIN FORMULA

Proctologist Developed Medicated Treatment



Drug Facts

Active ingredient

Lidocaine USP 5%.....Analgesic (pain relief)

Purpose

Uses

- helps relieve the local itching and discomfort associated with anorectal disorders or inflammation

Warnings

For external use only

- When using this product
- avoid contact with eyes

Drug Facts - Warnings (continued)

- 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
- symptoms clear up and return within a few days

Drug Facts - Warnings (continued)

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

- 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 daily
- children under 12 years of age: consult a doctor

DOCTOR BUTLERS HEMORRHOID AND FISSURE EXTERNAL PAIN FORMULA

lidocaine 5% ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70942-121	
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	
Inactive Ingredients				
Ingredient Name			Strength	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)				
TURMERIC (UNII: 856YO1Z64F)				
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)				
CARYA OVATA BARK (UNII: X765CF609L)				
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)				
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)				
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
CHOLESTEROL (UNII: 97C5T2UQ7J)				
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 9O3K93S3TK)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
HORSE CHESTNUT (UNII: 3C18L6RJAZ)				
ASIAN GINSENG (UNII: CUQ3A77YXI)				
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)				
ROSEMARY (UNII: IJ67X351P9)				
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)				
HELICHRYSUM ITALICUM FLOWER (UNII: P62Y550X24)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70942-121-01	28 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2022	
2	NDC:70942-121-11	28 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2022	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part346	03/01/2022	
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Labeler - Beyond Health, P.A. (026781064)

Registrant - Derma Care Research Labs (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derrma Care Research Labs		116817470	manufacture(70942-121)

Revised: 3/2023

Beyond Health, P.A.