DOCTOR BUTLER HEMORRHOID AND FISSURE ADVANCED FORMULA- glycerin 37.5%, lanolin 12.5%, lidocaine 4%, zinc oxide 5% ointment Beyond Health, PA

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 Advanced Formula

Glycerin 37.5%, Lanolin 12.5%, Lidocaine 4%, Zinc Oxide 5%

Anorectal (Hemorrhoidal)

Uses

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 avoid contact with eyes, do not exceed recommended dosage unless directed by a doctor. Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

Ask a doctor before use if you have allergies to any of the components of this product.

Stop use and ask a doctor if condition worsens or does not improve within seven days or bleeding occurs.

If pregnant or breastfeeding, ask a health care professional before use.

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

- 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 gently dry (patting or blotting) with tissue or soft cloth before use.
- The ointment can be applied using a gloved finger or finger cot.
- To use finger cots: roll one finger cot over finger. Gently squeeze ointment onto finger cot. Smooth a layer of the ointment over affected area or into anus.

Aesculus Hippocastanum (Horse Chestnut) Extract

Algae Extract

Argania Spinosa Kernel Oil

Benzyl Alcohol

Calendula Officinalis Flower Extract

Camellia Sinensis Leaf Extract

Cananga Odorata Flower Oil

Canola Oil

Caprylhydroxamic Acid

Caprylic/Capric Triglyceride

Centella Asiatica Extract

Chamomilla Recutita (Matricaria) Flower Extract

Cocos Nucifera (Coconut) Oil

Curcuma Longa (Turmeric) Root Extract

Euphorbia Cerifera (Candelilla) Wax

Glyceryl Caprylate

Helianthus Annuus (Sunflower) Seed Oil

Helianthus Annuus (Sunflower) Seed Wax

Hydrocortisone

Lavandula Angustifolia (Lavender) Oil

Linum Usitatissimum (Linseed) Seed Oil

Lysine HCl

Macadamia Ternifolia Seed Oil

Olea Europaea (Olive) Fruit Oil

Panax Ginseng Root Extract

Persea Gratissima (Avocado) Oil

Pogostemon Cablin Oil

Polyhydroxystearic Acid

Punica Granatum Fruit Extract

Ricinus Communis (Castor) Seed Oil

Rosa Canina Seed Oil

Sodium Hyaluronate

Tocopheryl Acetate

Triethoxycaprylylsilane

Viburnum Opulus Bark Extract

Water

Drug Facts (continued)

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

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- Adults: apply to the affected area up to 3 times daily.
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Drug Facts (continued)

Other information

Inactive ingredients

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Aesculus Hippocastanum (Horse Chestnut) Extract, Algae Extract, Argania Spinosa Kernel Oil, Benzyl Alcohol, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Cananga Odorata Flower Oil, Canola Oil, Caprylhydroxamic Aoid, Caprylic/Capric Triglyceride, Centella Asiatica Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cocos Nucifera (Coconut) Oil, Curcuma Longa (Turmeric) Root Extract, Euphorbia Cerifera (Candelilla) Wax, Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Aylorocortisone USP, Lavandula Angustilia (Lavender) Oil, Linum Usitatissimum (Linseed) Seed Oil, Lysine HCI. Macadamia Ternifolia Seed Oil, Olea Europaea (Olive) Fruit Oil, Panax Ginseng Root Extract, Persea Gratissima (Avocado) Oil, Pogostemon Cablin Oil, Polyhydroxystearic Acid, Punica Granatum Fruit Extract, Ricinus Communis (Castor) Seed Oil, Rosa Canina Seed Oil, Sodium Hyaluronate, Tocopheryl Acetate, Triethoxycaprylylsilane, Viburnum Opulus Bark Extract, Water. Viburnum Opulus Bark Extract, Water

www.DoctorButlers.com Distributed by: Beyond Health P.A. Tequesta, FL 33469 Phone: (561) 935-9698 Questions? Email us at Support@DoctorButlers.com

Contains Organic and Botanically Derived Natural Ingredients. Free From All Chemical Preservatives NO SULFATES, PARABENS, SYNTHETIC FRAGRANCE COMPOUNDS, OR RETINYL PALMITATE.







Contains Multiple Active Ingredients for a Comprehensive Solution and Enhanced Effectiveness



Doctor Butler's Hemorrhoid...(Advanced Formula 1.5 oz.)



NDC 70942-517-01

Helps to Relieve Itching & Discomfort Due to Inflamed Hemorrhoidal Tissue • For Temporary Relief of Pain, Soreness or Burning

"Leave the Pain Behind"™

Cruelty Free - No Animal Testing 📢

NET WT 1.5 OZ (42.5g)

Drug Facts	
Active ingredients	Purpose
Glycerin 37.5%	Protectant
Lanolin 12.5%	
Lidocaine 4.0%	Analgesic (pain relief)
Zinc Oxide 5.0%	Astringent
	→

Drug Facts (continued)

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

Warnings

For external and/or intrarectal use only

When using this product . Avoid contact with eyes Do not exceed recommended daily dosage unless directed by a doctor.

Drug Facts (continued)

Certain persons can develop allergic reactions to ingredients in this
product. If the symptom being treated does not subside or if redness,
irritation, swelling, pain, or other symptoms develop or increase,
discontinue use and consult a doctor.

Ask a doctor before use if you have:

· Allergies to any of the components of this product Stop use and ask a doctor if:

Condition worsens or does not improve within seven (7) days.

DOCTOR BUTLER HEMORRHOID AND FISSURE ADVANCED **FORMULA**

glycerin 37.5%, lanolin 12.5%, lidocaine 4%, zinc oxide 5% ointment

Product Information

HUMAN OTC DRUG Item Code (Source) NDC:70942-517 **Product Type**

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	37.5 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	12.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 g in 100 g

Inactive Ingredients

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Ingredient Name	Strength		
GLYCERYL CAPRYLATE (UNII: TM2TZ D4G4A)			
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			

HYALURONATE SODIUM (UNII: YSE9PPT4TH)
VIBURNUM OPULUS WHOLE (UNII: DIO510WJ04)
WATER (UNII: 059QF0KO0R)
ASIAN GINSENG (UNII: CUQ3A77YXI)
AVOCADO OIL (UNII: 6VNO72PFC1)
POMEGRANATE (UNII: 56687D1Z4D)
CANDELILLA WAX (UNII: WL0328HX19)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HYDROCORTISONE (UNII: W4X0X7BPJ)
CASTOR OIL (UNII: D5340Y2I9G)
ROSA CANINA SEED OIL (UNII: MHT97MG5P8)
MACADAMIA OIL (UNII: 515610SU8C)
OLIVE OIL (UNII: 6UYK2W1W1E)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)
SUNFLOWER OIL (UNII: 3W1JG795YI)
LAVENDER OIL (UNII: ZBP1YXW0H8)
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)
LINSEED OIL (UNII: 84XB4DV00W)
COCONUT OIL (UNII: Q9L0073W7L)
CHAMOMILE (UNII: FGL3685T2X)
CANOLA OIL (UNII: 331KBJ17RK)
CANANGA OIL (UNII: 8YOY78GNNX)
HORSE CHESTNUT (UNII: 3C18L6RJAZ)
TURMERIC (UNII: 856YO1Z64F)
ARGAN OIL (UNII: 4V59G5UW9X)
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)
BENZYL ALCOHOL (UNII: LKG8494WBH)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

ı	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:70942-517- 01	1 in 1 CARTON	09/20/2021		
	L	42.5 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	09/20/2021	

Registrant - Derma Care Research Labs (116817470)

Establishment			
Name	Address	ID/FEI	Business Operations
Derrma Care Research Labs		116817470	manufacture(70942-517)

Revised: 1/2023 Beyond Health, PA