

**DR BUTLERS HEMORRHOID AND FISSURE PF- 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.*

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**Dr Butler Hemorrhoid & Fissure Ointment PF**

Lidocaine 4%, Phenylephrine HCl 0.25%

Analgesic (pain relief), Vasoconstrictor

Temporarily shrinks hemorrhoidal tissue, for the temporary relief of pain, soreness, or burning, and helps relieve the local itching and discomfort associated with hemorrhoids.

**For external use only** including the skin of the anal canal.

**When using this product** do not exceed recommended daily dosage unless directed by a doctor, when using finger cots or an applicator, apply externally or the skin of the anal canal only. Do not put this product into the rectum.

**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, or 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, an allergic reaction develops, the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

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.

Aesculus hippocastanum (horse chestnut) extract, aloe barbadensis leaf extract, ascorbic acid, calendula officinalis flower extract, caprylhydroxamic acid, caprylic/capric triglyceride, centella asiatica extract, chamomile recutita (matricaria) flower extract, cholecalciferol, glycerin, glyceryl caprylate, helianthus annuus (sunflower) seed oil, hydrocortisone, laminaria digitata (algae) extract, lysine HCl, mineral oil, octyldodecanol, olea europaea (olive) fruit oil, panax ginseng root extract, PEG-8 dimehticone, petrolatum, porphyria umbilicalis extract, propylene glycol, punica granatum fruit extract, pyridoxine HCl, retinyl palmitate, silica, sodium hyaluronate, sodium propoxyhydroxypropyl thiosulfate silica, stearic acid, tocopheryl acetate,



Ingredient Name	Strength
<b>HORSE CHESTNUT</b> (UNII: 3C18L6RJAZ)	
<b>ALOE</b> (UNII: V5VD430YW9)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>TRICAPRYLIN</b> (UNII: 6P92858988)	
<b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U)	
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ)	
<b>LYSINE HYDROCHLORIDE</b> (UNII: JNJ23Q2COM)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)	
<b>PEG-8 DIMETHICONE</b> (UNII: GIA7T764OD)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PUNICA GRANATUM ROOT BARK</b> (UNII: CLV24I3T1D)	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>SODIUM PROPOXYHYDROXYPROPYL THIOSULFATE SILICA</b> (UNII: 208G222332)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70942-357-01	1 in 1 CARTON	02/20/2023	
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	02/20/2023	

**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(70942-357)

Revised: 2/2023

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