DR BUTLERS HEMORRHOID AND FISSURE PF- lidocaine 4.00, phenylephrine hydrochloride 0.25 ointment
Beyond Health P.A.

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, triethoxycaprylysilance, water, zea mays (corn) oil, zinc oxide

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

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lidocaine 4.00, phenylephrine hydrochloride 0.25 ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70942-357
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: 3W1JG795YI)	
HYDROCORTISONE (UNII: WI4X0X7BPJ)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
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)	
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)	
TRIETHOXYCAPRYLYLSILANE (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:70942-357-01	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 Drug	M015	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: 12/2024

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