FARGELIN HEMORRHOIDAL- calamine, petrolatum and phenylephrine hydrochloride ointment MADISON ONE ACME INC

Drug Facts

Active ingredients

Calamine 10.5% Petrolatum 79.25% Phenylephrine hydrochloride 0.25%

Purpose

Hemorrhoidal (anorectal) astringent/protectant Hemorrhoidal (anorectal) protectant Hemorrhoidal (anorectal) vasoconstrictor

Uses

temporarily helps relieve:

anorectal burning, itching, and discomfort associated with hemorrhoids temporarily:

reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders

shrinks hemorrhoidal tissue protects inflamed perianal skin and irritated areas

Warnings For rectal use only

Ask a doctor before use if you have

heart disease high blood pressure thyroid disease diabetes difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug for high blood pressure or depression

When using this product

in case of bleeding; consult a doctor promptly do not exceed the recommended daily dosage unless directed by a doctor do not use with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a doctor promptly.

Stop use and ask a doctor if

condition worsens symptoms do not improve within 7 days

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

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

Directions

- adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
 - For external hemorrhoids, apply a small amount of ointment directly to the affected area up to 4 times daily.
 - FOR INTRARECTAL USE (internal hemorrhoids): Attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Squeeze a small amount (2 g) of the ointment into the rectum. Remove and discard used applicator. Apply to the affected area up to 4 times daily.
- children under 12 years of age: consult a doctor.

Other information

keep container tightly closed store at room temperature 20 - 25 C (68 - 77 F) do not use if the physical properties of this product have changed

Inactive ingredients Amber, callicarpa nudiflora leaf, corydalis yanhusuo tuber, lanolin, panax notoginseng root, pearl, sanguisorba officinalis root, scutellaria baicalensis root, sodium borate, and styphnolobium japonicum flower.

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

FARGELIN HEMORRHOIDAL OINTMENT NDC 55614-610-01 0.705 oz (20 g) 04/06/2020

143mm

23mm ☑ 暫時緩解疼痛・瘙癢和灼痛 暫時舒耀傳續和 其他肛門直腸疾病疼痛 ② 収縮發炎和攤賬的組織 ☑ 舒緩和保護受刺激的部位 強力 內含遊樂器 40mm 痔瘡膏 Net Wt. 0.705 oz 盎可 (20g 克) 経路 28mm 最端 Made in China software mound has G.E.U. The state of the s b actors did gat annum

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HEMORRHOIDAL OINTMENT

HIGH STRENGTH

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NDC 55614-610-01

Temporary Pain Relief for Hemorrhoids & Other Anorectal Disorders

- Releves Temporary Pain, Itching and Burning
- Shrinks inflamed and Swotien Tissue
- Southes and Protects Irritate d Areas

Calamine | Petrolatum | Phenylephrine HCI

FARGELIN HEMORRHOIDAL

calamine, petrolatum and phenylephrine hydrochloride ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-610	
Route of Administration	TOPICAL, RECTAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10.3 g in 100 g	
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.05 g in 100 g	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	79.25 g in 100 g	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
AMBER (UNII: 70J9Z0J26P)	
CALLICARPA NUDIFLORA LEAF (UNII: IRA5LS3VXW)	
CORYDALIS YANHUSUO TUBER (UNII: 0TUP42692Z)	
LANOLIN (UNII: 7EV65EAW6H)	
PANAX NOTOGINSENG ROOT (UNII: GQX1C1175U)	
PEARL (HYRIOPSIS CUMINGII) (UNII: A75L5FZ 40U)	
SANGUISORBA OFFICINALIS ROOT (UNII: 4NYV2HT01X)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
STYPHNOLOBIUM JAPONICUM FLOWER (UNII: 644C3CSB6E)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:55614- 610-01	20 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	11/27/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	part346	11/27/2019	

Labeler - MADISON ONE ACME INC (096196758)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-610)	

Revised: 11/2024 MADISON ONE ACME INC