

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

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***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)

燙金

# FARGELIN HEMORRHOIDAL

calamine, petrolatum and phenylephrine hydrochloride ointment

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>AMBER</b> (UNII: 70J9Z0J26P)	
<b>CALLICARPA NUDIFLORA LEAF</b> (UNII: IRA5LS3VXW)	
<b>CORYDALIS YANHUSUO TUBER</b> (UNII: 0TUP42692Z)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>PANAX NOTOGINSENG ROOT</b> (UNII: GQX1C1175U)	
<b>PEARL (HYRIOPSIS CUMINGII)</b> (UNII: A75L5FZ40U)	
<b>SANGUISORBA OFFICINALIS ROOT</b> (UNII: 4NYV2HT01X)	
<b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)	
<b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)	
<b>STYPHNOLOBIUM JAPONICUM FLOWER</b> (UNII: 644C3CSB6E)	

## 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