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

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.

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)

High Strength Fargelin Ointment Box
SIZE: 143 × 40 × 23mm

04/06/2020

143mm

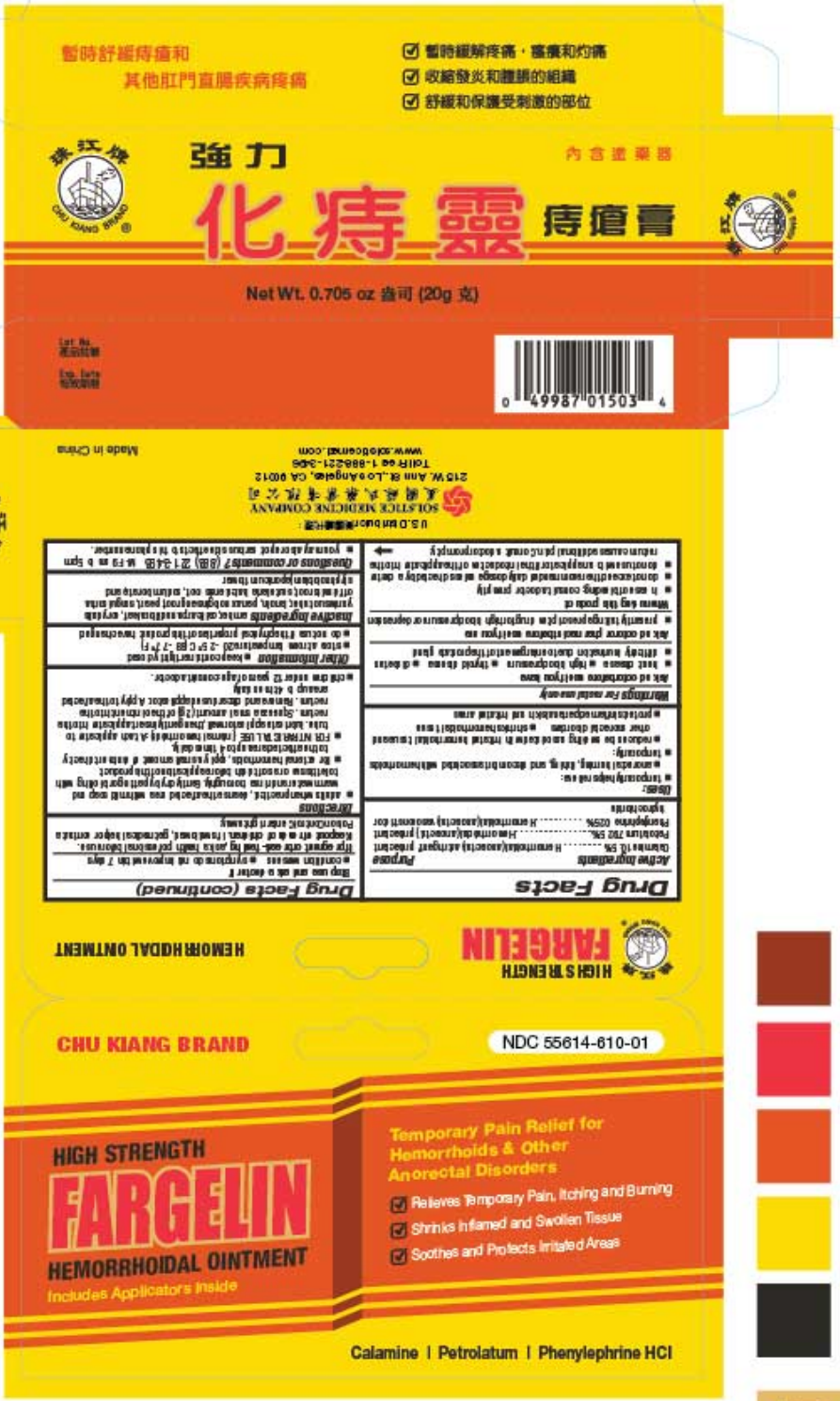
23mm

40mm

23mm

120mm

80mm



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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: A75L5FZ40U)	
SANGUISORBA OFFICINALIS ROOT (UNII: 4NYV2HT01X)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
STYPHNOLOBIUM JAPONICUM FLOWER (UNII: 644C3CSB6E)	

Packaging

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

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	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: 11/2022 MADISON ONE ACME INC