

MAYINGLONG BEZORNIL HEMORRHOIDAL - calamine, petrolatum, phenylephrine hydrochloride ointment

MAYINGLONG PHARMACEUTICAL GROUP CO LTD

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, lanolin, pearl, and sodium borate.

Questions or comments?

(888) 221-3496 M-F 9 am to 5 pm

MAYINGLONG BEZORNIL HEMORRHOIDAL OINTMENT NDC 30803-001-01 0.353 oz (10 g)

04.14.2011

Drug Facts
Active ingredients
 Calamine 10.5% Hemorrhoidal (anorectal) astringent/protectant
 Petrolatum 79.25% Hemorrhoidal (anorectal) protectant
 Phenylephrine hydrochloride 0.25% Hemorrhoidal (anorectal) vasoconstrictor

Purpose
 ■ 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

Uses

Drug Facts (continued)
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.

Drug Facts (continued)
 ■ FOR INTRARECTAL USE (internal hemorrhoids): Attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Squeeze a small amount (2g) 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

Drug Facts (continued)
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.

Drug Facts (continued)
 ■ 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, lanolin, pearl, and sodium borate.

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

Lot No. 有效期
 產品批號
 有效期限

MAYINGLONG BEZORNIL HEMORRHOIDAL OINTMENT
馬應龍痔瘡膏

NDC 30803-001-01
 Made in China

製造商: Manufactured by:
 馬應龍藥業集團股份有限公司
 Mayinglong Pharmaceutical Group Co. Ltd
 武漢湖北, 中國 Wuhan Hubei, China

美國總代理:
 U.S. Distributor:
SOLSTICE MEDICINE COMPANY
 美國蘇氏藥業有限公司
 215 West Ann Street, Los Angeles, CA 90012
 Toll Free: 1-888-221-3496 WWW.SOLSTICEMED.COM

- Pantone 201 C
- Pantone 130 C
- Pantone 123 C

NDC 30803-001-01

MAYINGLONG BEZORNIL HEMORRHOIDAL OINTMENT
馬應龍痔瘡膏

0.353 oz 盎司 (10 g 克)

製造商: Manufactured by:
 馬應龍藥業集團股份有限公司
 Mayinglong Pharmaceutical Group Co. Ltd
 武漢湖北, 中國 Wuhan Hubei, China Made in China

美國總代理:
 U.S. Distributor:
SOLSTICE MEDICINE COMPANY
 美國蘇氏藥業有限公司
 215 West Ann Street, Los Angeles, CA 90012
 Toll Free: 1-888-221-3496 WWW.SOLSTICEMED.COM

MAYINGLONG BEZORNIL HEMORRHOIDAL

calamine, petrolatum, phenylephrine hydrochloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30803-001
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	10.4 g in 100 g
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.05 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	79.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
AMBER (UNII: 70J9Z0J26P)	
LANOLIN (UNII: 7EV65EAW6H)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30803-001-01	10 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	08/28/2013	

Labeler - MAYINGLONG PHARMACEUTICAL GROUP CO LTD (526823828)**Establishment**

Name	Address	ID/FEI	Business Operations
MAYINGLONG PHARMACEUTICAL GROUP CO LTD		526823828	manufacture(30803-001)

Revised: 8/2013

MAYINGLONG PHARMACEUTICAL GROUP CO LTD