

HEMORRODIL UNGUENTO- zinc oxide ointment
ZURICH MEDICAL LABS, LLC

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.

Hemorrodil Unguento

Drug Facts

Active Ingredients

Zinc Oxide 5%

Categoría

Astringent

Use

For temporary relief of pain, soreness and burning. Helps relieve the local itching and discomfort. Temporarily shrinks hemorrhoidal tissue & provides a coating for relief of anorectal discomforts. Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warning

For external use only.

Do Not Use if: you are allergic to any ingredient in this formula. When using this product do not exceed the recommended daily dosage unless directed by a doctor do not put into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if: bleeding occurs; condition worsens or does not improve within 7 days; an allergic reaction develops; the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

- 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 by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with tissue or a soft cloth before applying ointment. Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.

For Intrarectal use: attach applicator to tube, lubricate applicator well, then gently insert applicator into the rectum; thoroughly cleanse applicator after each use and replace cover. Also apply ointment to external area.

Children under 12 years of age: ask a doctor.

Store at 20-25°C (68°-77°F)

Other Ingredients

Lanolin, petrolatum, purified H₂O, peanut oil, witch hazel, cod liver oil, polysorbate 80, cethyl alcohol, bees wax, glycerin, stearate, menthol, methyl & propyl paraben, bálsamo de Perú

PRINCIPAL DISPLAY PANEL - 28.35 g Tube Carton

Refreshing & soothes the pain of hemorrhoids

Net weight: 1oz (28.35g)

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502 NE 190th St. • Miami, FL 33179

Made in U.S.A.

HEMORRODIL

Hemorrhoidal Ointment

Datos del Medicamento
Ingrediente Activo Categoría Óxido de Zinc 5% Astringente
Usos: Ayuda temporalmente a combatir tejidos hemorroidales inflamados. Alivia temporal del dolor, picazón, sensación de quemazón y molestias producidas por los tejidos hemorroidales inflamados.
Precaución: Par a uso externo y/o intrarrectal solamente.
No usar si es alérgico a alguno de los ingredientes
Cuando use este producto no exceda la dosis recomendada a menos que sea indicada por un doctor.
Descontinúe su uso y consulte a su doctor si: La irritación del aplicador dentro del recto le produce dolor. Ocurra sangramiento o Su condición no mejora después de 7 días.
Consulte a su médico antes de usar el producto si: Está embarazada o es madre lactante
• Si tiene hemorroides sangrantes
• Es menor de 12 años • En caso de ingestión accidental, busque asistencia médica o póngase en contacto con un Centro de Toxicología de inmediato
Manténgalo fuera del alcance de los niños
Instrucciones: Limpie el área afectada con agua y jabón y seque con un material suave. Aplíquese libremente en el área afectada hasta 5 veces al día, preferiblemente al acostarse, en la mañana y después de cada evacuación. PARA USO INTRARRECTAL: Enrosque el aplicador al tubo, lubrique el aplicador bien y suavemente introduzca en el recto.
Otra Información: Almacénese a temperaturas entre 15 - 30°C (59 - 86°F)
Otros Ingredientes: Lanolina, petrolato, agua D.I., aceite de mani, agude hamamelis, aceite de higado de bacalao, polisorbato tween 80, alcohol cetílico, cera de abeja, gliceri monostearato, peg 6 estearato, mentol, propyl y methyl paraben, bálsamo de Perú

Refresca, y alivia el dolor de las hemorroides

HEMORRODIL

Peso Neto: 1OZ (28.35g)

UNGÜENTO HEMORROIDAL

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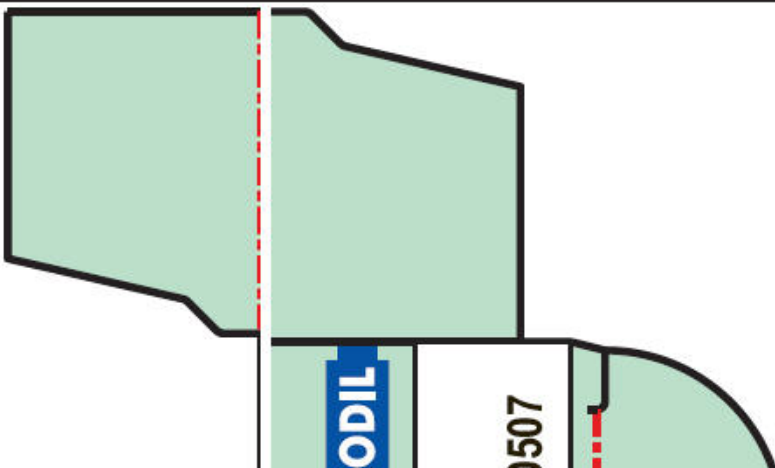
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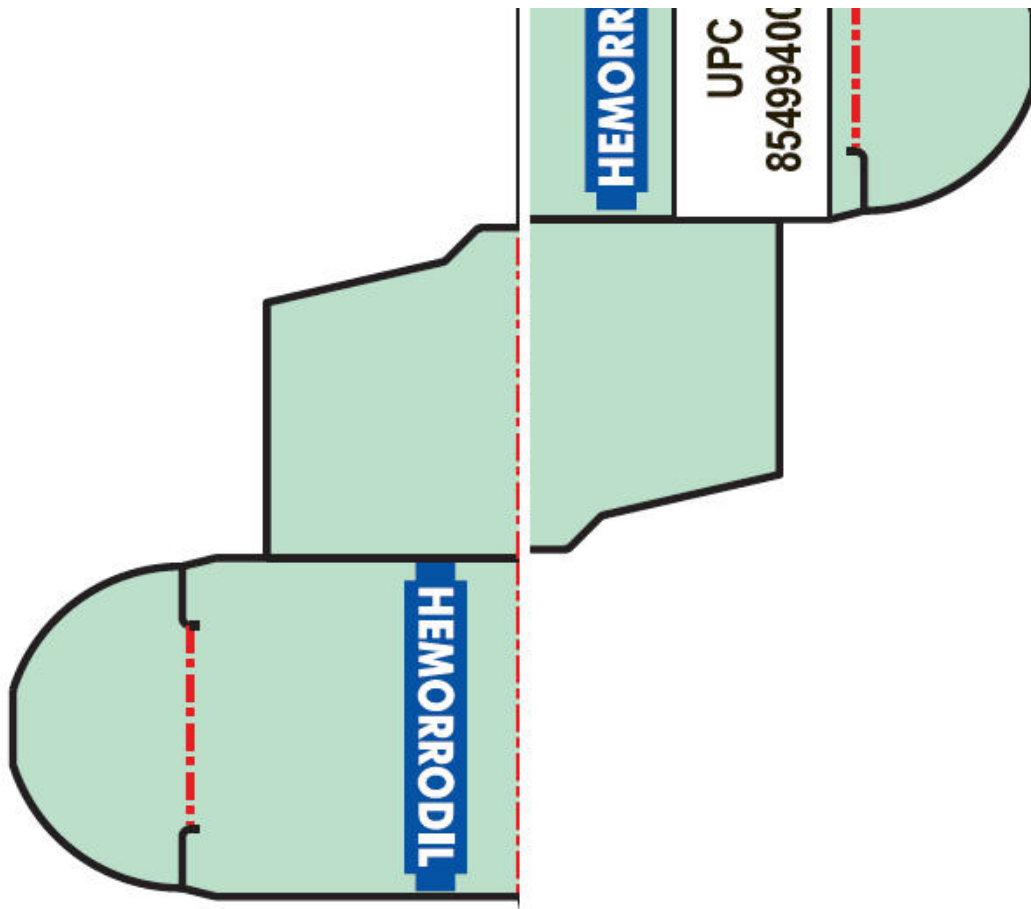
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HEMORRODIL UNGUENTO

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61357-130
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WITCH HAZEL (UNII: 101I4J0U34)	
PEANUT OIL (UNII: 5TL50QU0W4)	
COD LIVER OIL (UNII: BBL281NWFQ)	
MENTHOL (UNII: L7T10EIP3A)	
BALSAM PERU (UNII: 8P5F881OCY)	
LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

PEG-6 STEARATE (UNII: 8LQC57C6B0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61357-130-01	1 in 1 CARTON		
1		28.35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	03/01/1964	

Labeler - ZURICH MEDICAL LABS, LLC (071904097)

Establishment

Name	Address	ID/FEI	Business Operations
ZURICH MEDICAL LABS, LLC		071904097	MANUFACTURE(61357-130)

Revised: 3/2014

ZURICH MEDICAL LABS, LLC