

HEMORRODIL- phenylephrine hydrochloride and cocoa butter suppository
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® Supositorios

Drug Facts

Active Ingredients	Purpose
Phenylephrine Hydrochloride 0.25%	Vasoconstrictor
Cocoa Butter 88.44%	Protectant

Uses

- Temporarily shrinks hemorrhoidal tissues
- Provides temporary relief from the itching, burning and discomfort associated with hemorrhoids
- Aids in protecting irritated anorectal areas

Warning

For rectal use only

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.

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

When using this product

- do not exceed recommended daily dose unless directed by a doctor
- in case of bleeding or if condition worsens or does not improve within 7 days, consult a doctor promptly.

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

- detach one suppository from the strip. Remove wrapper before inserting into rectum
- gently insert suppository into rectum up to 4 times daily, especially at night, in the morning or after each bowel movement.

Children under 12 years of age, consult a doctor

Other information

Store at temperature 59° – 86°F

Inactive ingredients

methylparaben, propylparaben, starch

PRINCIPAL DISPLAY PANEL - 12 Suppository Blister Pack Carton

HEMORRODIL®

*Soothing &
Refreshing*

12 SUPPOSITORIES

Datos del Medicamento (continuación) Indicaciones: Adultos (continuación) Los niños menores de 12 años de edad, consulte a un médico Otra información Almacene a temperatura 59° - 86° F Ingredientes inactivos metilparabeno, propilparabeno, almidón													
Datos del Medicamento <table border="1"> <thead> <tr> <th>Ingredientes activos</th> <th>Propósito</th> </tr> </thead> <tbody> <tr> <td>Clohidrato de Fenilefrina 0,25 %</td> <td>Vasoconstrictor</td> </tr> <tr> <td>Manteca de Cacao 88,44 %</td> <td>Protector</td> </tr> </tbody> </table>	Ingredientes activos		Propósito	Clohidrato de Fenilefrina 0,25 %	Vasoconstrictor	Manteca de Cacao 88,44 %	Protector	Drug Facts <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Phenylephrine Hydrochloride 0.25%</td> <td>Vasoconstrictor</td> </tr> <tr> <td>Cocoa Butter 88.44%</td> <td>Protectant</td> </tr> </tbody> </table>	Active Ingredients	Purpose	Phenylephrine Hydrochloride 0.25%	Vasoconstrictor	Cocoa Butter 88.44%
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Uso <ul style="list-style-type: none"> Temporalmente contrae los tejidos hemorroidales Proporciona alivio temporal de la comezón, ardor y las molestias asociadas con las hemorroides Ayuda en proteger las áreas anorrectales irritadas Advertencia: Para uso rectal solamente Pregúntele a su médico o farmacéutico antes de usarlo si estas actualmente tomando un medicamento recetado, para la presión arterial alta o la depresión. Pregúntele a su médico antes de usarlo si usted tiene: <ul style="list-style-type: none"> enfermedades del corazón enfermedades de las tiroides presión arterial alta diabetes dificultad para orinar debido al agrandamiento de la glándula prostática Al usar este producto <ul style="list-style-type: none"> no exceda la dosis recomendada a menos que lo indique un médico en caso de sangramiento o si las condiciones empeoran o no mejoran en 7 días, consulte a un médico de inmediato. Si está embarazada o lactando, pregúntele a un profesional de la salud antes de usar. Manténgalo fuera del alcance de los niños		Uses <ul style="list-style-type: none"> Temporarily shrinks hemorrhoidal tissues Provides temporary relief from the itching, burning and discomfort associated with hemorrhoids Aids in protecting irritated anorectal areas Warning: For rectal use only Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression. Ask a doctor before use if you have: <ul style="list-style-type: none"> heart disease high blood pressure thyroid disease diabetes difficulty in urination due to enlargement of the prostate gland When using this product <ul style="list-style-type: none"> do not exceed recommended daily dose unless directed by a doctor in case of bleeding or if condition worsens or does not improve within 7 days, consult a doctor promptly. 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.											
Datos del Medicamento (continuación) En caso de ingestión, obtenga ayuda médica o contacte un Centro de Control de Envenenamiento inmediatamente. Indicaciones: Adultos solamente: <ul style="list-style-type: none"> desprendan un supositorio de la tira. Quite la envoltura antes de introducirlo en el recto introduzca suavemente el supositorio en el recto: hasta 4 veces diario, especialmente por la noche, por la mañana o después de cada evacuación 		Drug Facts (continued) Directions: Adults: <ul style="list-style-type: none"> detach one suppository from the strip. Remove wrapper before inserting into rectum gently insert suppository into rectum up to 4 times daily, especially at night, in the morning or after each bowel movement. Children under 12 years of age, consult a doctor Other information Store at temperature 59° – 86°F Inactive ingredients methylparaben, propylparaben, starch											

Refresca y Alivia

HEMORRODIL®

Marca Registrada

Soothing & Refreshing

12 SUPPOSITORIES 12 SUPPOSITORIES

502 NE 190th St • Miami, FL 33179

zürich medical labs

Made in U.S.A.
Hecho en U.S.A.

PC-228.00

HEMORRODIL

phenylephrine hydrochloride and cocoa butter suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1357-135
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	1768.8 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 1357-135-01	1 in 1 CARTON		
1		12 in 1 BLISTER PACK		

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(6 1357-135)

Revised: 3/2014

ZURICH MEDICAL LABS, LLC