

MIRACTIL- hemorrhoidal cream gel
POLIMEROS Y SERVICIOS S.A-

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.

Submission for Miractil Hemorrhoidal Cream

Detail showing Active Ingredient from package

Active ingredients.jpg

Information shown both on container label and package

Drug Facts	
Active ingredients:	Purposes
Cocoa butter 12.5%.....	Protectant
Glycerin 12.5%,.....	Protectant
Menthol 0.1%.....	Analgesic, antipruritic, anesthetic
White petrolatum 15%.....	
Zinc oxide 12.5%,.....	Protectant

Detail showing Inactive ingredient from package

Inactive ingredinets.jpg

Information shown both on cntainer label and package

Drug Facts (continued)
Inactive ingredients: carbomer, chitosan, demineralized purified water, methyl paraben, phosphate buffer, polycarbophile, propyl paraben, white mineral oil gel

Detail showing Purpose within Active Ingredients from package

Purpose.jpg

Information shown both on container label and package

Drug Facts

Active ingredients:

Purposes

Cocoa butter 12.5%.....	Protectant
Glycerin 12.5%,.....	Protectant
Menthol 0.1%.....	Analgesic, antipruritic, anesthetic
White petrolatum 15%.....	Protectant
Zinc oxide 12.5%,.....	Protectant

Detail showing Indications from package

Indications.jpg

Information shown both on container label and package

Drug Facts

Indications:

- For the temporary relief of local pain, itching, burning and discomfort associated with hemorrhoids.
- Temporarily protects inflamed, irritated anorectal surfaces from irritation and abrasion during bowel movements.
- Temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues. ■ May provide a cooling sensation.

Detail showing Instructions for use and named Directions from package

Directions.jpg

Information shown both on container label and package

Drug Facts (continued)

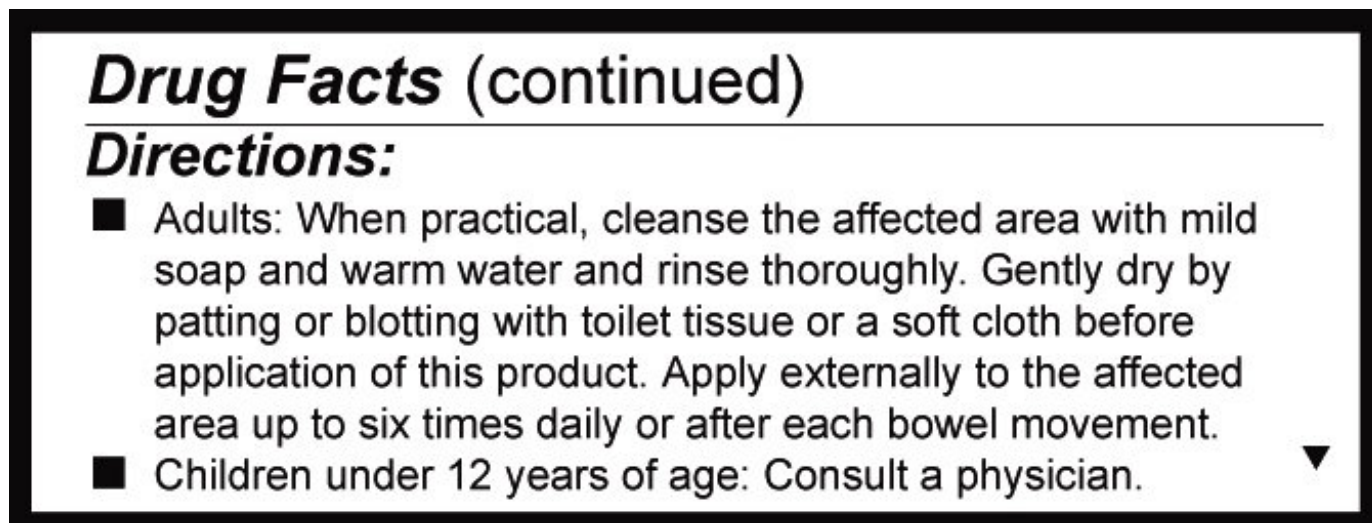
Directions:

- 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. Apply externally to the affected area up to six times daily or after each bowel movement.
- Children under 12 years of age: Consult a physician.

Detail showing Dosage and Administration within Directions from package

Dosage and administration.jpg

Information shown both on container lable and package



Drug Facts (continued)

Directions:

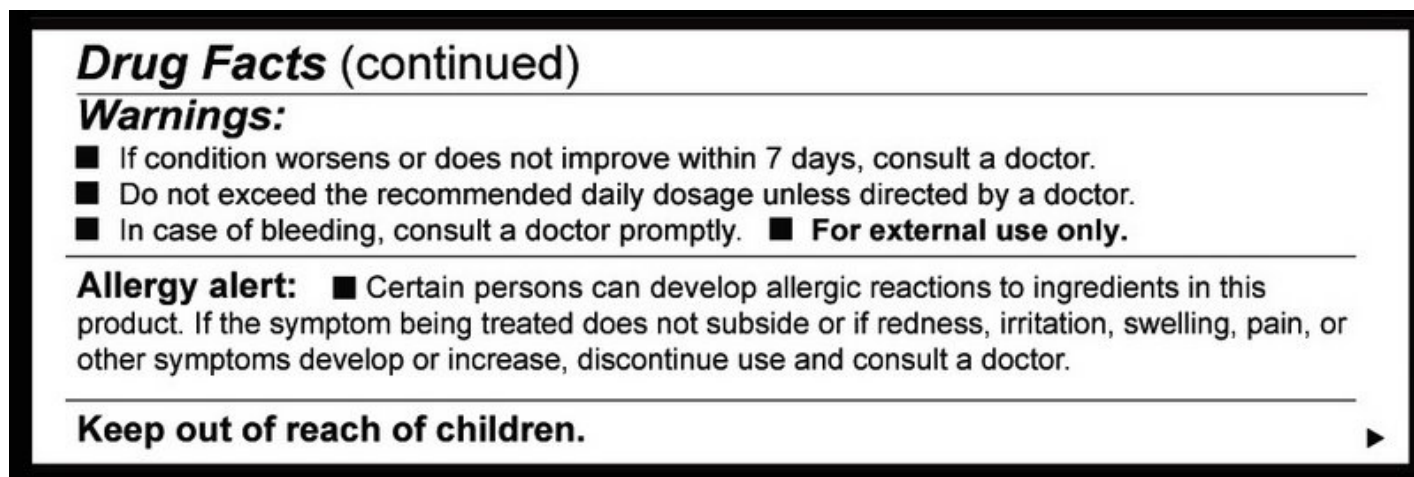
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Detail showing Warnings from package

Warnings.jpg

Information shown both on container label and package



Drug Facts (continued)

Warnings:

- If condition worsens or does not improve within 7 days, consult a doctor.
- Do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, consult a doctor promptly. ■ **For external use only.**

Allergy alert: ■ Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

Keep out of reach of children.

▶

Detail showing Keep Out of Reach of Children within Warnings from package

Keep out of reavh of children.jpg

Information shown on package

Drug Facts (continued)

Warnings:

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 - Do not exceed the recommended daily dosage unless directed by a doctor.
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-

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Keep out of reach of children.



Detail showing Questions from package

Questions or comments.jpg

Information shown both on container label and package

Questions or comments? Call weekdays 9 am to 5 pm CST
1-888-621-1255 or 1-832-877-3784



Detail showing Other Safety Information from package

Other information.jpg

Information shown both on container label and package

Other information:

Best if stored between 40° F and 90° F



Representative sample image of carton/container label

Container label.jpg

General view of inner container label



Package content of labeling.jpg

General view of box content of labeling

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 ■ Children under 12 years of age: Consult a physician

Other Information: Best if stored between 40° F and 90° F

Inactive ingredients: carbomer, chitosan, demineralized purified water, methyl paraben, orthosilicic acid, phosphate buffer, polycarbophile, propyl paraben, white mineral oil gel

Questions or comments? Call weekdays 9 am to 5 pm CST **1-888-621-1255 or 1-832-877-3784** ☎

Miractil Hemorrhoidal Cream
 Superior Polyelectrolyte Technology

Drug Facts

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Soothes Irritation

- Polyelectrolyte technology releases the active ingredients in a controlled manner for lasting relief
- No need for intrarectal application
- Alleviates internal and external pain
- No stickiness or stains on clothes

Net Weight: 1.06 oz (30g)

Indications:
 ■ For the temporary relief of local pain, itching, burning and discomfort associated with hemorrhoids.
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 ■ Temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues. ■ May provide a cooling sensation.

Do Not Use if seal under cap is broken or missing. This package contains an outer carton. Do not buy if outer carton is missing.

Manufactured by Polimeros y Servicios, S.A. San Jose, Costa Rica
 Distributed by Med-Actil, LLC, 1625 23rd St. Galveston TX 77550
www.med-actil.com

hemorrhoidal cream gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69492-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	125 mg in 1 g
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	125 mg in 1 g
MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	1 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	125 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CHITOSAN MEDIUM MOLECULAR WEIGHT (200-400 MPA.S) (UNII: 5GV09YMO52)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ORTHO SILICIC ACID (UNII: 623B93YABH)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POLYCARBOPHIL (UNII: W25LM17A4W)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69492-011-06	1 in 1 BOX	03/04/2019	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	05/20/2015	

Labeler - POLIMEROS Y SERVICIOS S.A.- (815740251)

Establishment

Name	Address	ID/FEI	Business Operations
POLIMEROS Y SERVICIOS S.A.		815740251	manufacture(69492-011)

