

MAJOR PREP HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hydrochloride ointment
Major Pharmaceuticals

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	Purpose
Mineral oil 14%.....	Protectant
Petrolatum 71.9%.....	Protectant
Phenylephrine HCl 0.25%.....	Vasoconstrictor

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue and relieves burning
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings For external and/or intrarectal use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

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

When using this product do not use more than the recommended daily dosage

Stop use and ask a doctor if

- bleeding occurs
- condition gets worse or does not get better within 7 days
- introduction of the applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a physician before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- children under 12 years of age: ask a doctor
- adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe
- gently dry by patting or blotting with a tissue or a soft cloth before applying
- when first opening tube, remove foil seal
- for intrarectal use: remove protective cover from applicator and attach to tube
- lubricate applicator well, then gently insert applicator into the rectum
- thoroughly clean applicator and replace protective cover after each use

- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- also apply ointment to external area

Other information store at 20° to 25°C (68° to 77°F)

Inactive ingredients glycerin, lanolin, methylparaben, propylparaben, stearyl alcohol, thyme oil, tocopherol acetate, water, white wax


Distributed By

Major Pharmaceuticals

31778 Enterprise Drive

Livonia, MI 48150

Made in Korea

<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are now taking a prescription drug for high blood pressure or depression</p> <p>When using this product do not use more than the recommended daily dosage</p> <p>Stop use and ask a doctor if ■ bleeding occurs ■ condition gets worse or does not get better within 7 days ■ introduction of the applicator into the rectum causes additional pain</p> <p>If pregnant or breast-feeding, ask a physician before use. ▶</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ children under 12 years of age: ask a doctor ■ adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe ■ gently dry by patting or blotting with a tissue or a soft cloth before applying ■ when first opening tube, remove foil seal ■ for intrarectal use: remove protective cover from applicator and attach to tube and lubricate applicator well, then gently insert applicator into the rectum ■ thoroughly clean applicator and replace protective cover after each use</p>								
<p>Drug Facts (continued)</p> <p>■ apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement ■ also apply ointment to external area</p> <p>Other information store at 20° to 25° C (68° to 77° F)</p> <p>Inactive ingredients butylated hydroxytoluene, concentrated glycerin, glyceryl monostearate, methylparaben, propylparaben, purified lanolin, purified water, shark liver oil, thyme oil red</p> <p>Questions or Comments? (800) 616-2471</p>	<p>TAMPER-EVIDENT: Do not use if "FOIL SEAL" is broken or missing.</p> <p>Distributed by: MAJOR® PHARMACEUTICALS 31778 Enterprise Drive Livonia, MI 48150 M-110 Rev. 11/12 Re-Order No. 700329</p>  <p>Made in Korea</p>								
<p>MAJOR NDC 0904-6319-02</p> <p>MAJOR-PREP™ Hemorrhoidal Ointment</p> <p>With Applicator</p> <p>NET WT 2 OZ (57 g)</p> <p>*Compare to the active ingredients of Preparation H®</p>									
<p>(RETAIN CARTON FOR COMPLETE LABEL INFORMATION)</p> <p>Drug Facts</p> <table border="0"> <tr> <td>Active ingredients</td> <td>Purpose</td> </tr> <tr> <td>Mineral oil 14%</td> <td>Protectant</td> </tr> <tr> <td>Petrolatum 71.9%</td> <td>Protectant</td> </tr> <tr> <td>Phenylephrine HCl 0.25%</td> <td>Vasoconstrictor</td> </tr> </table>	Active ingredients	Purpose	Mineral oil 14%	Protectant	Petrolatum 71.9%	Protectant	Phenylephrine HCl 0.25%	Vasoconstrictor	<p>Drug Facts (continued)</p> <p>Uses ■ helps relieve the local itching and discomfort associated with hemorrhoids ■ temporarily shrinks hemorrhoidal tissue and relieves burning ■ temporarily provides a coating for relief of anorectal discomforts ■ temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful</p> <p>Warnings For external and/or intrarectal use only</p>
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6319
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Route of Administration TOPICAL, RECTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	719 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
THYME OIL (UNII: 2UK410MY6B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6319-02	1 in 1 CARTON		
1		57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/30/2013	

Labeler - Major Pharmaceuticals (191427277)

Revised: 6/2013

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