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.

Active ingredients	Purpose
Mineral oil 14%	Protectant
Petrolatum 74.9%	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 of pharmacist before use if you are now taking a prescription drug for high blood pressure or depression

When using this product do not exceed 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

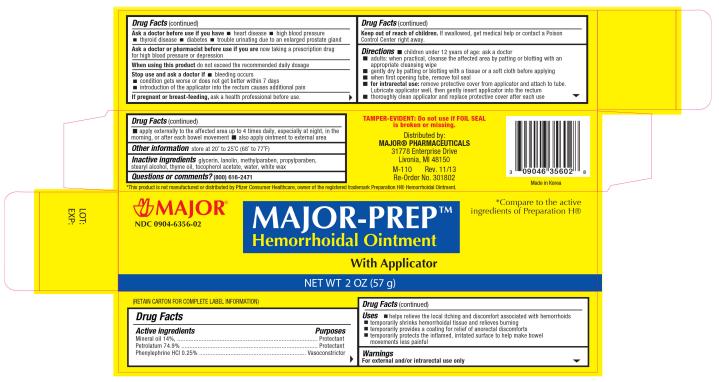
Distributed By

Major Pharmaceuticals

31778 Enterprise Drive

Livonia, MI 48150

Made in Korea



MAJOR PREP HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hydrochloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6356
Route of Administration	RECTAL, TOPICAL		

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	749 mg in 1 g
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

Ina	active Ingredien	ts			
		Ingredient Name			Strength
GL	YCERIN (UNII: PDC6	A3C0OX)			
LA	NOLIN (UNII: 7EV65)	EAW6H)			
ME	THYLPARABEN (UN	II: A2I8C7HI9T)			
PRO	OPYLPARABEN (UN	II: Z8IX2SC1OH)			
STI	EARYL ALCOHOL (UNII: 2KR8914H1Y)			
тн	YME OIL (UNII: 2UK	410 MY6 B)			
TO	COPHEROL (UNII: R	0ZB2556P8)			
TO	COFILEROL (UNII. R				
WA	ATER (UNII: 059QF0K	COOR)			
WA WH	ATER (UNII: 059QF0K HTE WAX (UNII: 7G1)	COOR)			
WA WH Pa	ATER (UNII: 059QF0K HTE WAX (UNII: 7G1) Ackaging	COOR) I5DA97F)		Marketing Start Date	Marketing End Dat
WA WH Pa	ATER (UNII: 059QF0K AITE WAX (UNII: 7G1) ACKaging Item Code	COOR) (5DA97F) Package Description		Marketing Start Date	Marketing End Date
WA WH ₽a #	NTER (UNII: 059QF0K NTE WAX (UNII: 7G1) NCKaging Item Code NDC:0904-6356-02	COOR) (5DA97F) Package Description 1 in 1 CARTON	-	Marketing Start Date 10/11/2016	Marketing End Date
WA WH Pa #	NTER (UNII: 059QF0K NTE WAX (UNII: 7G1) NCKaging Item Code NDC:0904-6356-02	COOR) (5DA97F) Package Description	-	0	Marketing End Date
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WA WH # 1 N 1	NTER (UNII: 059QF0K NTE WAX (UNII: 7G1) NCKaging Item Code NDC:0904-6356-02	COOR) (5DA97F) Package Description 1 in 1 CARTON 57 g in 1 TUBE; Type 0: Not a Combination	-	0	Marketing End Date
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Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2016

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