

APJ HEMORRHOIDAL - phenylephrine hydrochloride, mineral oil, petrolatum ointment
A P J Laboratories Limited

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.

PHENYLEPHRINE HYDROCHLORIDE

PETROLATUM

MINERAL OIL

Protectant

Vasoconstrictor

If swallowed, get medical help or contact a Poison Control Center right away.

- 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.

For external and/or intrarectal use only

- 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 ointment.
- when first opening the tube, puncture foil seal with top end of cap
- apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- intrarectal use:
 - remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum
 - thoroughly cleanse applicator after each use and replace cover
- also apply ointment to external area
- regular use provides continual therapy for relief of symptoms
- children under 12 years of age: ask a doctor

PARAFFIN

BUTYLATED HYDROXYTOLUENE

METHYLPARABEN

PROPYLPARABEN
 CHLOROCRESOL
 LANOLIN
 MAGNESIUM STEARATE
 LIGHT MINERAL OIL

DISPLAY PANEL



APJ HEMORRHOIDAL

phenylephrine hydrochloride, mineral oil, petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46084-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.55 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	720 mg in 1 g
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	40 mg in 1 g
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	70 mg in 1 g
METHYLPARABEN (UNII: A2I8C7HI9T)	.1 mg in 1 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	.1 mg in 1 g
CHLOROCRESOL (UNII: 36W53O7109)	.02 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	.5 mg in 1 g
MAGNESIUM STEARATE (UNII: 70097M6I30)	1 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	10 mg in 1 g

Product Characteristics

Color	white (OFF WHITE)	Score	
Shape		Size	

Flavor		Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:46084-111-10	28 g in 1 TUBE	
2	NDC:46084-111-20	57 g in 1 TUBE	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/01/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment			
Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-111)

Revised: 6/2013

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