

HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hcl ointment

Padagis Israel Pharmaceuticals Ltd

Hemorrhoidal Ointment Drug Facts

Active ingredients

Mineral oil 14%

Petrolatum 74.9%

Phenylephrine HCl 0.25%

Purposes

Protectant

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
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug for high blood pressure or depression.

When using this product

do not exceed the recommended daily dosage unless directed by a doctor

Stop use and ask a doctor if

- bleeding occurs
- condition worsens or does not improve within 7 days
- introduction of applicator into the rectum causes additional pain

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. (1-800-222-1222)

Directions

- 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

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) oil, tocopheryl acetate, white wax

Questions or comments?

1-800-719-9260

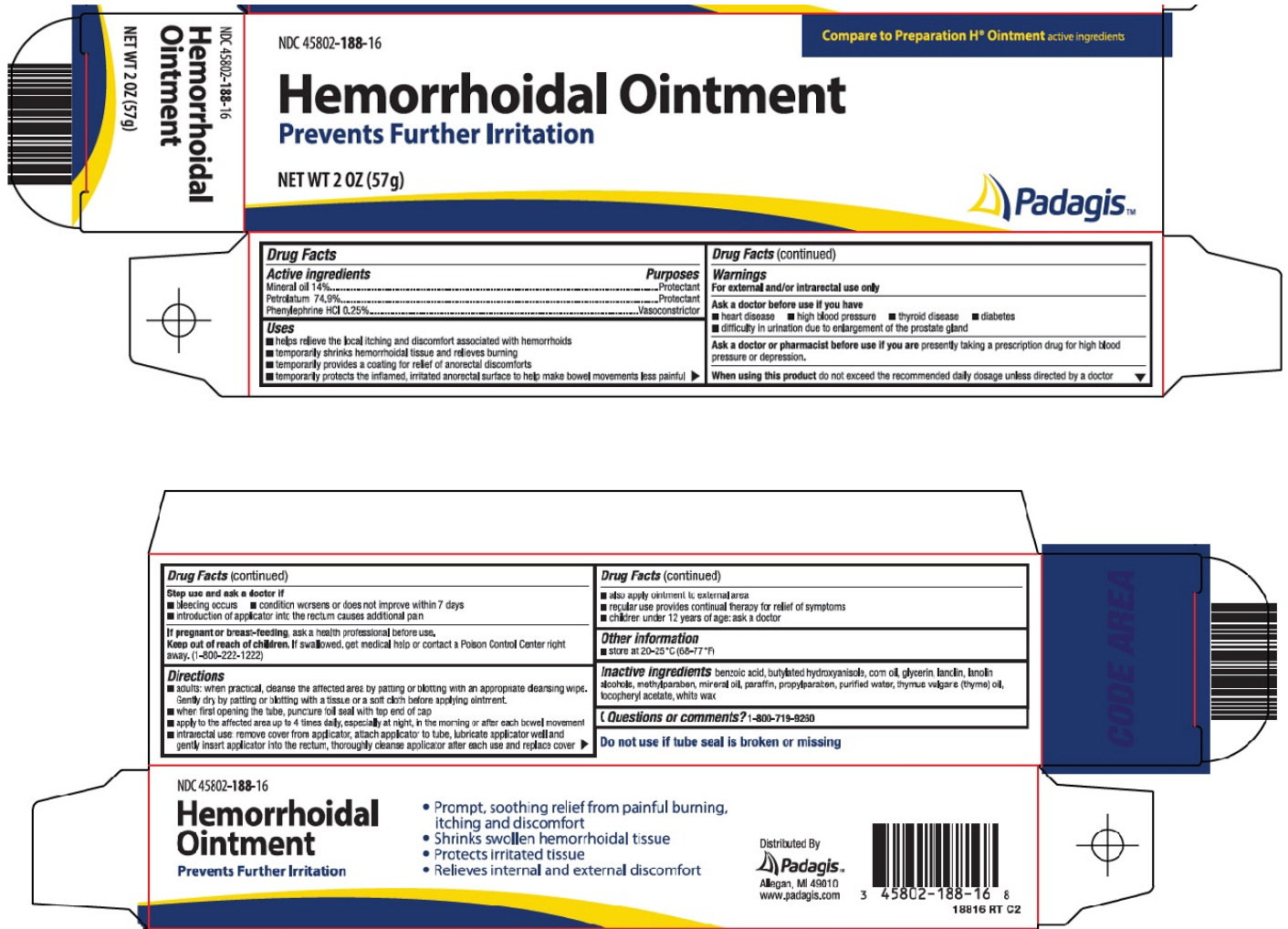
Package/Label Principal Display Panel

Compare to Preparation H[®] Ointment active ingredients

Hemorrhoidal Ointment

Prevents Further Irritation

NET WT 2 OZ (57 g)



HEMORRHOIDAL			
mineral oil, petrolatum, phenylephrine hcl ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-188
Route of Administration	RECTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)		MINERAL OIL	14 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)		PETROLATUM	74.9 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CORN OIL (UNII: 8470G57WFM)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
THYME OIL (UNII: 2UK410MY6B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics

Color	YELLOW (light)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-188-16	1 in 1 CARTON	11/01/2013	
1		57 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 Drug	M015	11/01/2013	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)