

SMART SENSE HEMORRHOIDAL- mineral oil, petrolatum and phenylephrine hydrochloride ointment

Kmart Corporation

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.

Kmart Corporation Hemorrhoidal Ointment Drug Facts

Active ingredients

Mineral oil 14%

Petrolatum 71.9%

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, shark liver oil, thymus vulgaris (thyme) oil, tocopheryl acetate, white wax

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

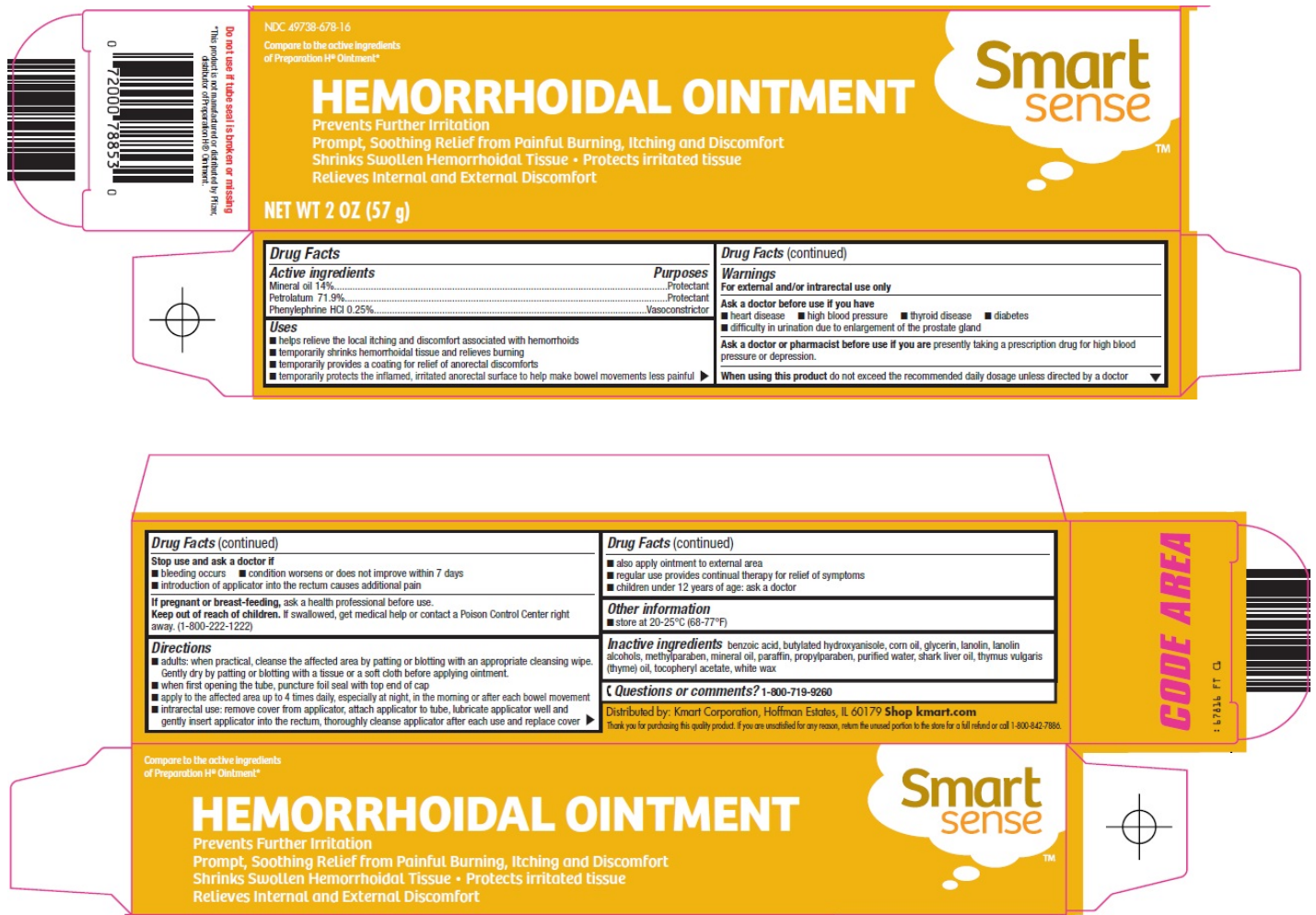
Compare to the active ingredients of Preparation H® Ointment

HEMORRHOIDAL OINTMENT

Prevents Further Irritation

Prompt, Soothing Relief from Painful Burning, Itching and Discomfort

Shrinks Swollen Hemorrhoidal Tissue
 Protects irritated tissue
 Relieves Internal and External Discomfort



SMART SENSE HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:49738-678
Route of Administration	RECTAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (MINERAL OIL)	MINERAL OIL	140.000 mg in 100 g
PETROLATUM (PETROLATUM)	PETROLATUM	719.000 mg in 100 g
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	2.500 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID	
BUTYLATED HYDROXYANISOLE	
CORN OIL	
GLYCERIN	
LANOLIN	
LANOLIN ALCOHOLS	
METHYLPARABEN	
PARAFFIN	
PROPYLPARABEN	
WATER	
SHARK LIVER OIL	
THYME OIL	
.ALPHA.-TOCOPHEROL ACETATE	
WHITE WAX	

Product Characteristics			
Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-678-16	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	01/15/2013	

Labeler - Kmart Corporation (008965873)