

**HEMORRHOIDAL CREAM PRO- phenylephrine hcl, petrolatum, mineral oil cream  
ASTONEA LABS PRIVATE 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.*

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**Astonea Hemorrhoidal Cream**

**Drug Facts**

Mineral Oil (14% w/w)..... Skin Protectant

Petrolatum (74.9% w/w)..... Skin Protectant

Phenylephrine HCl (0.25% w/w)..... Vasoconstrictor

**Uses**

- Helps relieve the anorectal symptoms associated with hemorrhoids (pain, soreness, burning)
- Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders

**Warnings**

**For external 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
- do not put into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**

- bleeding occurs
- condition worsens or does not improve within 7 days
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

**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.

### Directions

- Adults: when possible, clean affected area with mild soap or warm water, rinse thoroughly, and then gently dry (patting or blotting) with tissue or soft cloth before use
- To use applicator, attach it to the tube, lubricate well, then gently insert part way into anus and squeeze tube to deliver medication. Thoroughly cleanse applicator after use with mild soap and warm water and rinse thoroughly
- Apply externally to the affected area up to 4 times daily, especially at night, when waking up and after each bowel movement
- Children under 12 years of age: ask a doctor

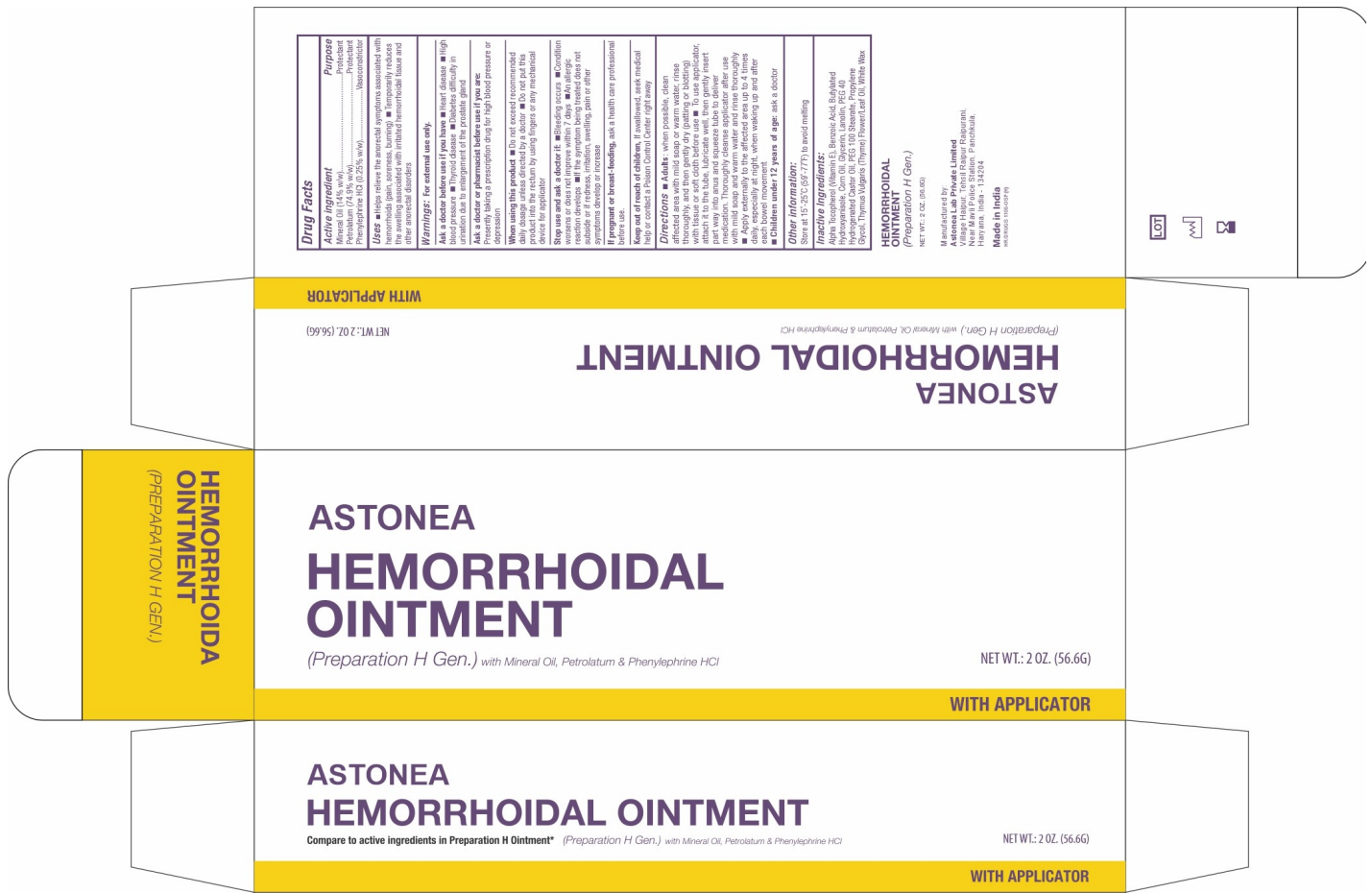
### Other information

store at 20-25°C (68-77°F)

### Inactive ingredients

Alpha Tocopherol (Vitamin E), Benzoic Acid, Butylated Hydroxyanisole, Corn Oil, Glycerin, Lanolin, PEG-40 Hydrogenated Castor Oil, PEG-100 Stearate, Propylene Glycol, Thymus Vulgaris (Thyme) Flower/Leaf Oil, White Wax

## PRINCIPAL DISPLAY PANEL



## HEMORRHOIDALCREAMPRO

phenylephrine hcl, petrolatum, mineral oil cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-410
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MINERAL OIL</b> (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	14 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	74.9 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYOXYL 100 STEARATE</b> (UNII: YD01N1999R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>THYMUS VULGARIS LEAF</b> (UNII: GRX3499643)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-410-55	56.6 g in 1 TUBE; Type 0: Not a Combination Product	10/05/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	10/05/2022	

**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)

