

**HEMORRHOIDALCREAMPRO- phenylephrine hcl, petrolatum, mineral oil cream
ASTONEA LABS PRIVATE LIMITED**

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

Drug Facts	
Active ingredient	Purpose
Mineral Oil 14.6% (w/w) Phenylephrine HCl 0.25% (w/w) Petrolatum 75.15% (w/w)	Pruritic Hemorrhoids
Uses	Warnings
Relieves itching and discomfort associated with hemorrhoids (pain, soreness, burning). Temporarily reduces swelling and irritation associated with internal hemorrhoidal tissue and external hemorrhoids.	For external use only. Do not use if you are allergic to any of the ingredients listed above. Do not use if you have a known hypersensitivity to any of the ingredients listed above. Do not use if you have a known hypersensitivity to any of the ingredients listed above. Do not use if you have a known hypersensitivity to any of the ingredients listed above.
Directions	Other information
Apply externally to the affected area up to 4 times daily, especially at night, when waking up and after defecation. Apply to the affected area up to 4 times daily, especially at night, when waking up and after defecation. Apply to the affected area up to 4 times daily, especially at night, when waking up and after defecation.	Store at 15°-25°C (59°-77°F) to avoid melting. 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.

HEMORRHOIDALCREAMPRO
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Product Information

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

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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	74.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WHITE WAX (UNII: 7G1J5DA97F)	
THYMUS VULGARIS LEAF (UNII: GRX3499643)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CORN OIL (UNII: 8470G57WFM)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (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 Drug	M015	10/05/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)