

**ATOPALM HEMORRHOIDAL - mineral oil, petrolatum, phenylephrine  
hydrochloride ointment  
NeoPharm USA**

*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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**ATOPALM Hemorrhoidal Ointment**

**Active Ingredients**

Mineral Oil 14%  
Petrolatum 71.9%  
Phenylephrine HCl 0.25%

**Purpose**

Protectant  
Protectant  
Vasocostrictor

**Uses**

- for temporary relief of 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 using if you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

**Ask a doctor of 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 the 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 immediately or contact a Poison Control Center right away.

**Directions**

**Do not use if foil seal under cap is broken or missing.**

- 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 externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for intrarectal use, remove cover from the applicator, attach applicator to tube, lubricate applicator well, then 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.

store at 20° – 25°C (68° – 77°F)

**Inactive Ingredients**

COD LIVER OIL, GLYCERIN, LANOLIN, BEES WAX, SQUALANE, CHOLESTEROL, MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA, STEARIC ACID, BUTYLATED HYDROXYTOLUENE, METHYLPARABEN, PARAFFIN, PROPYLPARABEN, PURIFIED WATER, SODIUM BENZOATE, THYMUS VULGARIS (THYME) FLOWER/LEAF OIL, TOCOPHERYL ACETATE.

**Questions or information call toll free**

1-855- ATOPALM

**ATOPALM Hemorrhoidal Ointment 2oz (51141-0230-2)**

**Outer Package**

# ATOPALM™

## HEMORRHOIDAL OINTMENT

Soothing Ointment provides rapid Relief from Painful Burning and Itching ■ Relieves Internal and External Discomfort ■ Shrinks Swollen Hemorrhoidal Tissue ■ Helps Protect Irritated Tissue

**RAPID, SOOTHING RELIEF**

# ATOPALM™

## HEMORRHOIDAL OINTMENT

With US Patented **M L E** Technology



Net Wt. 2 oz/56 g

Rapid relief  
for irritated  
tissue

Soothing Ointment provides rapid Relief from Painful Burning and Itching

### Drug Facts

Active Ingredients	Purpose
Mineral Oil 14%	Protectant
Petrolatum 71.9%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor

**Uses** ■ for temporary relief of 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 using if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland.

### Drug Facts (continued)

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 the 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 immediately or contact a Poison Control Center right away.

**Other Information** ■ store at 20°–25°C (68°–77°F)

### Drug Facts (continued)

**Directions** Do not use if foil seal under cap is broken or missing. ■ **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 externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement ■ for intrarectal use, remove cover from the applicator, attach applicator to tube, lubricate applicator well, then 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.

### Drug Facts (continued)

#### Inactive Ingredients

COD LIVER OIL, GLYCERIN, LANOLIN, BEES WAX, SQUALANE, CHOLESTEROL, MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA, STEARIC ACID, BUTYLATED HYDROXYTOLUENE, METHYLPARABEN, PARAFFIN, PROPYLPARABEN, PURIFIED WATER, SODIUM BENZOATE, THYMUS VULGARIS (THYME) FLOWER/LEAF OIL, TOCOPHERYL ACETATE.

**Questions or information call toll free:** 1-855-ATOPALM

US Patent # US 6221371B1

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea 75728

## Inner Package

**RAPID RELIEF DELIVERED IN A MOISTURIZING, SKIN OINTMENT**

# ATOPALM™

## HEMORRHOIDAL OINTMENT

With US Patented **M L E** Technology



Net Wt. 2 oz / 56 g

**Rapid, soothing relief from painful burning, itching and discomfort ■ Shrinks swollen hemorrhoidal tissue  
■ Protects irritated tissue ■ Relieves external discomfort ■ Temporarily protects the inflamed, irritated  
anorectal surface to help make bowel movements less painful**

**Active Ingredients** Mineral Oil 14%; Petrolatum 71.9%; Phenylephrine HCl 0.25%

**Uses** for temporary relief of burning; helps relieve local itching and discomfort associated with hemorrhoids, temporarily shrinks hemorrhoidal tissue, 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 drug for high blood pressure or depression. When using this product do not exceed recommended dose 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. Keep out of reach of children. If swallowed get medical help immediately or contact a Poison Control Center right away. If pregnant or breast feeding, ask a health professional before use.

**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 soft tissue or cloth before applying cream. When first opening tube, puncture foil seal with top end of the cap. Apply up to 4 times daily, especially at night, in the morning and 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° to 25°C (68° to 77°F). Questions or information call toll free: 1-855 ATOPALM

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea #75728

## ATOPALM HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hydrochloride ointment

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0230
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
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	71.9 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>COD LIVER OIL</b> (UNII: BBL281NWFG)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA</b> (UNII: 1211AIM8G7)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>METHYL PARABEN</b> (UNII: A2I8C7H9T)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>THYME OIL</b> (UNII: 2UK410MY6B)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0230-2	1 in 1 CARTON		
1		56 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/18/2012	

**Labeler** - NeoPharm USA (965502912)**Establishment**

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture(51141-0230)

Revised: 7/2012

NeoPharm USA