

ATOPALM HEMORRHOIDAL PAIN RELIEVING - glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream
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.

ATOPALM Hemorrhoidal Pain Relieving Cream

Active Ingredient

Glycerin 14.4%
Phenylephrine HCl 0.25%
Pramoxine HCl 1%
White Petrolatum 15%

Purpose

Protectant
Vasoconstrictor
Local Anesthetic
Protectant

Uses

for temporary relief of pain, soreness and burning ■ helps relieve the local itching and discomfort associated with hemorrhoids ■ temporarily shrinks hemorrhoidal tissue ■ 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 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 ■ do not put into the rectum by using fingers or an 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 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 cream ■ when first opening the tube, puncture foil seal with top end of cap ■ apply externally or in the lower portion of the anal canal only ■ apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement ■ for application in the lower anal canal, remove cover from the dispensing cap. Attach dispensing cap to tube, Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus. ■ thoroughly cleanse dispensing cap after each use and replace cover.

Children under 12 years of age

■ ask a doctor.

■ store at 68° – 77°F (20° – 25°C)

Inactive Ingredients

WATER, CETYL ALCOHOL, POLYSORBATE 60, GLYCERYL STEARATE, STEARIC ACID, MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA, CHOLESTEROL, ALOE VERA GEL, METHYLPARABEN, PROPYLPARABEN.

Questions or information call toll free

1-855- ATOPALM

Product Labeling

Rapid Soothing Pain Relief

US Patented Technology

ATOPALM

HEMORRHOIDAL PAIN RELIEVING CREAM

With US Patented MLE Technology

Rapid Relief from Painful Burning, Itching, External Discomfort, Shrinks Swollen Hemorrhoidal Tissue

Soothing cream with pain relieving ingredient. Temporarily Protects Irritated Tissue, Rapid Relief from External Discomfort

Strong Pain Relief – Soothes Irritated Hemorrhoidal Tissue

Net Wt. 1 oz /28.3 g

US Patent # US 6221371B1

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

Made in Korea

ATOPALM™

HEMORRHOIDAL PAIN RELIEVING CREAM

**Rapid Soothing
Pain Relief**

Drug Facts

Active Ingredients	Purpose
Glycerin 14.4%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local Anesthetic
White Petrolatum 15%	Protectant

Uses for temporary relief of pain, soreness and burning ■ helps relieve the local itching and discomfort associated with hemorrhoids ■ temporarily shrinks hemorrhoidal tissue ■ 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 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 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 an 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 immediately or contact a Poison Control Center right away.

Drug Facts (continued)

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

US Patent # US 6221 371B1

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

Made in Korea

75720

**Rapid Soothing
Pain Relief**



**US Patented
Technology**

ATOPALM™
HEMORRHOIDAL PAIN RELIEVING CREAM
With US Patented **M L E** Technology



*Rapid Relief from Painful Burning, Itching, External Discomfort,
Shrinks Swollen Hemorrhoidal Tissue*

ATOPALM™

*Soothing cream with pain relieving ingredient. Temporarily Protects
Irritated Tissue, Rapid Relief from External Discomfort*

Strong Pain Relief – Soothes Irritated Hemorrhoidal Tissue

ATOPALM™
HEMORRHOIDAL PAIN RELIEVING CREAM
With US Patented **M L E** Technology



Net Wt. 1 oz/28.3 g

Rapid Pain Relief delivered in a Moisturizing, Skin Cream

ATOPALM™

HEMORRHOIDAL PAIN RELIEVING CREAM



With US Patented **M L E** Technology

Net Wt. 1 oz / 28.3 g

Rapid soothing relief from painful burning, itching and discomfort ■ Shrinks swollen hemorrhoidal tissue ■ Temporarily protects irritated tissue ■ Relieves external discomfort

Active Ingredients Glycerin 14.4%; Phenylephrine HCl 0.25%; Pramoxine HCl 1%; White Petrolatum 15%.

Uses: for temporary relief of pain, soreness and burning ■ helps relieve local itching and discomfort associated with hemorrhoids ■ temporarily shrinks hemorrhoidal tissue.

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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 externally or in the lower portion of the anal canal only. ■ Apply up to 4 times daily, especially at night, in the morning and after a bowel movement. Children under 12 years of age ■ ask a doctor.

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

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ATOPALM HEMORRHOIDAL PAIN RELIEVING

glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1.0 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0220-1	1 in 1 CARTON		
1		28.3 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/17/2012	

Labeler - NeoPharm USA (965502912)

Revised: 1/2012

NeoPharm USA