

**NIKZON HEMORRHOIDAL- glycerin, petrolatum, phenylephrine hydrochloride, and pramoxine hydrochloride cream**  
**Genomma Lab USA**

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**Nikzon® Hemorrhoidal Cream**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Glycerin 14.4%	Protectant
Petrolatum 15%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local Anesthetic

**Uses**

- for the temporary relief of anorectal itching and discomfort associated with hemorrhoids, anorectal disorders, inflamed hemorrhoidal tissues, or piles

**Warnings**

**For external use only.**

**Do not use this product**

- in the eyes or nose
- if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

**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 apply to large areas of the body
- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a physician if**

- bleeding occurs
- the condition worsens or does not improve within 7 days
- an allergic reaction develops
- the symptom being treated does not subside or redness, irritation, swelling or pain develops, persists, or increases

**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: 800-222-1222.

## Directions

- Adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing pad. Gently dry by patting or blotting with a tissue or a soft cloth before applying cream
- apply externally to the affected area up to 4 times daily or after each bowel movement
- children under 12 years old: consult a physician

## Other Information

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

## Inactive ingredients

BHA, cetyl alcohol, citric acid, decolorized aloe vera barbadensis leaf juice, disodium EDTA, glycerin, glyceryl stearate, laureth-23, methylparaben, mineral oil, panthenol, petrolatum, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, sodium carboxymethyl cellulose, steareth-2, steareth-20, stearyl alcohol, tocopherol (vitamin E) acetate, xanthan gum

## Questions or comments?

**1 877 99 GENOM (43666)** Monday to Friday, 8 AM to 6 PM Central time

Distributed by: Genomma Lab USA, Inc., Houston, TX, 77027

## PRINCIPAL DISPLAY PANEL - 25.5 g Tube Carton

Nikzon®

HEMORRHOIDAL  
(ANORECTAL) CREAM

Temporary relief from:

- Pain
- Itching
- Inflammation

Net Wt. 0.9 Oz (25.5 g)



# NIKZON HEMORRHOIDAL

glycerin, petrolatum, phenylephrine hydrochloride, and pramoxine hydrochloride cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50066-010
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Glycerin</b> (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	144 mg in 1 g
<b>Petrolatum</b> (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	150 mg in 1 g
<b>Phenylephrine hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine hydrochloride	2.5 mg in 1 g
<b>Pramoxine hydrochloride</b> (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine hydrochloride	10 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>mineral oil</b> (UNII: T5L8T28FGP)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-010-09	1 in 1 CARTON	11/01/2024	
1		25.5 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph drug	M015	11/01/2024	

**Labeler** - Genomma Lab USA (832323534)

### Establishment

Name	Address	ID/FEI	Business Operations
Natureplex, LLC		062808196	MANUFACTURE(50066-010)

Revised: 11/2024

Genomma Lab USA