

**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 doctor 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 increase. 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 toilet 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 doctor.

## **Other Information**

- Store at 20 to 25°C (68 to 77°F).
- Close cap tightly after use.

## **Inactive ingredients**

Aloe Barbadensis Leaf Extract, Butylated Hydroxytoluene, Cetearth-12, Glyceryl Stearate SE, Mineral Oil, Panthenol, Phenoxyethanol, Purified Water, Sodium hydroxide, Stearic Acid, Vitamin E, Xanthan Gum.

## **Questions or comments?**

US 1-877-994-3666 Monday to Friday from 8 AM to 6 PM, Central time. Dominican Republic:18887600140

Distributed by:

U.S.: Genomma Lab USA Inc., Houston, TX 77098.

## **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 | HEMORROIDES  
[ANORECTAL] CREAM      CREMA [ANORECTAL]

Fast Relief from Hemorrhoids  
Rápido Alivio de Hemorroides

Helps relieve the local itching and discomfort associated with hemorrhoids.  
Ayuda a aliviar el prurito y las molestias asociadas con las hemorroides.

Net Wt. 0.9 OZ [ 25.5 g]



- Paraben-free      Libre de parabenos
- Alcohol-free      Libre de alcohol
- pH balanced      pH balanceado

PL14008  
W03

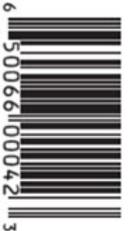
# Nikzon

HEMORRHOIDAL | HEMORROIDES  
[ANORECTAL] CREAM      CREMA [ANORECTAL]

Temporary relief from:  
Alivio temporal de:

- Pain / Dolor
- Itching / Comezón
- Inflammation / Inflamación

Net Wt. 0.9 Oz [ 25.5 g]



**Información del medicamento** (Continuation)  
**Indicaciones:** • Adultos: Cuando sea posible, limpie el área afectada dando palmaditas o secando suavemente usando una toallita limpiadora adecuada. • Seque suavemente dando palmaditas o secando con papel higiénico o un paño suave antes de aplicar la crema. • Aplique externamente en la zona afectada hasta 4 veces al día o después de cada evacuación intestinal. • Niños menores de 12 años: Consulte a un médico.  
**Contraindicaciones:** • No use este producto si tiene una reacción alérgica al ingrediente activo o a cualquiera de los excipientes.  
**Precauciones:** • Si está embarazada o amamantando, consulte a un profesional de la salud antes de usarlo.  
**Advertencias:** • Si esta embarazada o amamantando, consulte a un profesional de la salud antes de usarlo.  
**Uso:** • Para el alivio temporal de la comezón y el malestar anorectal asociado con hemorroides, trastornos anorrectales, tejidos hemorroidales inflamados o alérgicos (hemorroides).  
**Propósito:** • Protector  
 Glicerina 14.4%  
 Propileno Glicol 15%  
 Polidimetilsiloxano 0.25%  
 Vasocostrictor  
 Pramoxina HCl 1%  
 Anestésico local

**Drug Facts** (continued)  
**Warnings:** • For the temporary relief of anorectal itching and discomfort associated with hemorrhoids, anorectal disorders, inflamed hemorrhoidal tissues, or piles.  
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**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 the product into the rectum by using fingers or any mechanical device or applicator.  
**Stop use and ask a doctor 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, persists, or increases.  
**If pregnant or breast-feeding, ask a health professional before use.**  
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Distribuido por:  
 U.S. Genomma Lab USA Inc., Houston, TX 77098, R.O. Genomma Lab Dominicana, S.R.L., Santo Domingo, R.D.  
 Rep. Dom., Mfr. / Fab. / Qual. Control

Central (continued)  
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# 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>cetareth-12</b> (UNII: 7V4MR24V5P)	
<b>glyceryl stearate SE</b> (UNII: FCZ5MH785I)	
<b>mineral oil</b> (UNII: T5L8T28FGP)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	

## 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	07/07/2025	
1		25.5 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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OTC monograph drug	M015	07/07/2025	
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**Labeler** - Genomma Lab USA (832323534)

**Establishment**

Name	Address	ID/FEI	Business Operations
Quality CDMO		117658386	MANUFACTURE(50066-010)

Revised: 7/2025

Genomma Lab USA