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

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# Nikzon® Hemorrhoidal Cream

# **Drug Facts**

Active ingredients	Purpose
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)

#### HEMORRHOIDAL | HEMORROIDES (ANORECTAL) CREAM CREMA (ANORECTAL)

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

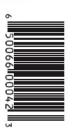
Net Wt. 0.9 OZ (25.5 g)

Rápido Alivio de Henorio de de la composição de la compos

Helps relieve the local itching and discomfort associated with hemorrhoids

Ayuda a aliviar comezón y molestias asociadas con las hemorroides.

PL 1400B V03



<u>Hemorrhoidal | Hemorroides</u> (ANORECTAL) CREAM

#### Temporary relief from: Alivio temporal de:

- Pain / Dolor
- \* Itching/Comezón
- nation/Infla

Net Wt. 0.9 0z (25.5 g)

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

Questions or comments? 1877 99 GENOM (43666) Monday to Friday,

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Drug Facts (continued)

SPreguntas? 1877 99 GENOM (43666)
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Editactio de Alos evan (Alos Barbadesia), BHA, Carboxime®icelulosa Sódica.
Glocelino, Laureth 23, Metilperalbon, Alostie miensal, Pariendi, Proprietado, Proprietado, Proprietado, Proprietado (Aleitoperalbon), Alostie miensal, Pariendi (Proprietado), Condiçõe de Barcadio de Sodio, Esteseth 20, Esteseth (Aconto), Conderdo (Meimes El Matuelli, Vitamina El, Agua (Pumicada)).
Petrolato bisono, Coma Suntana. Ingredientes Inactivos

Información del Medicamento (Continuación)

Other Information = store at 15 to 30°C (59 to 86°F) = Tamper Evident:

To NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

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Local Anesthetic	Pramoxine HCI 1%
otoitenoooseV	Phenylephrine HCI 0.25%
nstoetor9	Pétrolatum 15%
netoetor9	Glycerin 14.4%
esodin <sup>q</sup>	Active ingredients

Drug Facts

# Almacarar a temperatura ambientea 15-30°C (59-86°F) • Cerrar firmemente è tapa después de tuar Información Adicional

 Para niños menores de 12 años: consulte a su médico. Vojudne crip ueuropo poga ej auea specpaga com mua caba gejdaga prasza 4 veces aj quar Remueva la tapa y levante el sello de aluminio del fubo.
 Abudinos cuando se adrique, lavar el eles esteñadas con jabon susve y agua plas y unique cudadosamenta. Secar suavementa con pequeños góbjecitos con un idealla de papel o un tapo limitio antas de aplicar esta producto.

Manienga fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o póngase en contacto con un Centro de Control de Envenenamiemb.

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Durante el uso de este producto - no exceda la dosía diaria recomendada, a menos de que su médico lo indique - no aplicar este producto dentro del recto mediante el uso de dedos u otros dispositivos. pousugo nu megicamento recetado para la inperiensión artenar o la depresión.

Solo para uso externo

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para ofinar debido aita - entermedad de la trioides • diabetes • difficultad

para ofinar debido aita - entermedad de la próstata.

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Pregulinte a su madramento perada de la troses y la depresión

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**SEIONEMENDA** 

ntlamado o hemorroides. **Usos •** Pera el alivio temporal de comezón anorectal, ardor y molestias asociadas con hemorroides y afecciones anorectales, tejido hemorroidal infilando o hemorroides.

	11 11 1 2 1 1
Anestésico local	Pramoxina HCI 1%
Vasoconstrictor	Fenilefrina HQ 0.25%
Protector Protector	Petrolato 15%
notbeton 9	Glicerina 1 4.4%
otisogorq	Ingredientes Activos

Información del Medicamento

# **NIKZON HEMORRHOIDAL**

glycerin, petrolatum, phenylephrine hydrochloride, and pramoxine hydrochloride cream

# **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-010
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**Route of Administration** TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	144 mg in 1 g	
Petrolatum (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	
Pramoxine hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine hydrochloride	10 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
cetyl alcohol (UNII: 936JST6JCN)			
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)			
mineral oil (UNII: T5L8T28FGP)			
xanthan gum (UNII: TTV12P4NEE)			
propylene glycol (UNII: 6DC9Q167V3)			

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	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 In	formation		
Marketing	Application Number or Monograph	Marketing Start	<b>Marketing End</b>

Category	Citation	Date	Date
OTC monograph drug	M015	11/01/2024	

# Labeler - Genomma Lab USA (832323534)

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

Revised: 11/2024 Genomma Lab USA