NIKZON HEMORRHOIDAL- phenylephrine hydrochloride and pramoxine hydrochloride cream
Genoma Lab USA Inc

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.

Nikzon®
Hemorrhoidal Cream

Drug Facts

Active ingredients	***Purpose***
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local anesthetic

Uses

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

Warnings

For external use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty urinating due to enlarged prostate gland.

Ask a doctor or pharmacist before use if you are

- 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 this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

- rectal bleeding occurs
- an allergic reaction occurs
- the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase
- condition worsens or does not improve within 7 days.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Remove cap and lift foil safety seal from tube.
- Adults: When practical, cleanse the affected area with mild soap and warm water, and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Apply externally to the affected area with a thin layer up to 4 times daily.
- Children under 12 years of age: consult a doctor.

Other information

- Store at room temperature 15-30°C (59-86°F)
- Close cap tightly after use.

Inactive ingredients

Aloe Vera (Aloe Barbadensis) Extract, BHA, Carboxymethylcellulose Sodium, Cetearyl Alcohol, Citric Acid, Edetate Disodium, Glycerin, Glyceryl Stearate, Laureth 23, Methylparaben, Mineral Oil, Panthenol, Propyl Gallate, Propylene Glycol, Propylparaben, Sodium Benzoate, Steareth 2, Steareth 20, Stearyl Alcohol, Tocopherol (Natural Vitamin E), Vitamin E, Water (Purified), White Petrolatum, Xanthan Gum.

Questions?

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 g Tube Box

Nikzon®

HEMORRHOIDAL
(ANORECTAL) CREAM

Temporary relief from:

- Pain
- Itching
- Inflammation

Net Wt. 0.9 Oz (25 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 g)

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 g)

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

6 50066 00042 3

Directions ▪ Remove cap and lift foil safety seal from tube.
▪ Adults: When practical, cleanse the affected area with mild soap and warm water, and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. ▪ Apply externally to the affected area with a thin layer up to 4 times daily.
▪ Children under 12 years of age: consult a doctor.

Other information
▪ Store at room temperature 15-30°C (59-86°F) ▪ Close cap tightly after use.

Inactive ingredients
Aloe Vera (Aloe Barbadensis) Extract, BHA, Carboxymethylcellulose Sodium, Cetearyl Alcohol, Citric Acid, Edetate Disodium, Glycerin, Glyceryl Stearate, Laureth 23, Methylparaben, Mineral Oil, Panthenol, Propyl Gallate, Propylene Glycol, Propylparaben, Sodium Benzoate, Steareth 2, Steareth 20, Stearyl Alcohol, Tocopherol (Natural Vitamin E), Vitamin E, Water (Purified), White Petrolatum, Xanthan Gum.

Questions? 1 877 99 GENOM (43666) Monday to Friday, 8 am to 6 pm Central time.

Información del Medicamento (Continuación)

Ingredientes Inactivos
Extracto de Aloe vera (Aloe Barbadensis), BHA, Carboximetilcelulosa Sódica, Alcohol Cetearílico, Ácido Cítrico, Edetato Disódico, Glicerina, Estearato de Glicerilo, Laureth 23, Metilparabeno, Aceite mineral, Pantenol, Propilgalato, Propilenglicol, Propilparabeno, Benzoato de Sodio, Esteareth 2, Esteareth 20, Estearil Alcohol, Tocoferol (Vitamina E Natural), Vitamina E, Agua (Purificada), Petrolato blanco, Goma Xantana.

¿Preguntas? 1 877 99 GENOM (43666)
Lunes a Viernes, 8 am a 6 pm Tiempo del centro.

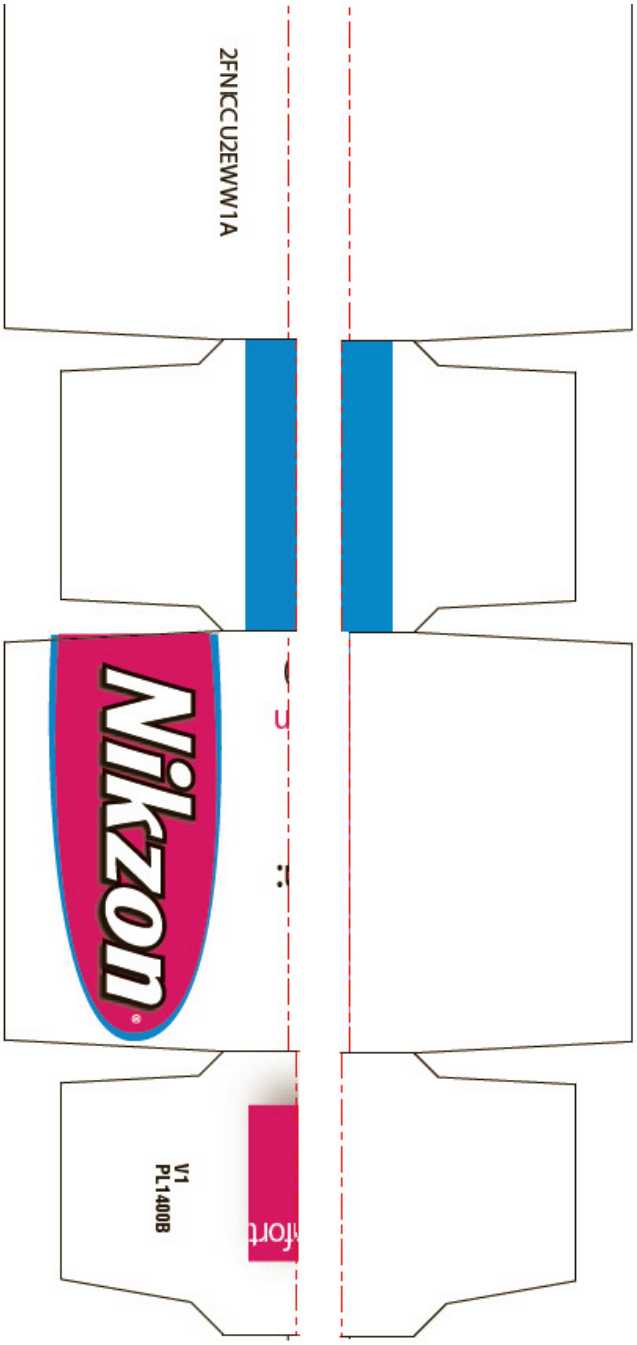
Indicaciones
▪ Remueva la tapa y levante el sello de aluminio del tubo.
▪ Adultos: cuando se aplique, lavar el área afectada con jabón suave y agua tibia y enjuague cuidadosamente. Secar suavemente con pequeños golpecitos con un toalla de papel o un trapo limpio antes de aplicar este producto.
▪ Aplique cubriendo toda el área afectada con una capa delgada hasta 4 veces al día.
▪ Para niños menores de 12 años: consulte a su médico.

Información Adicional
▪ Almacenar a temperatura ambiental 15-30°C. (59-86°F) ▪ Cerrar firmemente la tapa después de usar.

Manténga fuera del alcance de los niños. En caso de ingestión, obtenga ayuda medica o póngase en contacto con un Centro de Control de Envenenamiento.

▪ se produce una reacción alérgica ▪ el síntoma no desaparece o si el enrojecimiento, hinchazón, dolor u otros síntomas aumentan
▪ el padecimiento empeora o no mejora en 7 días.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



Drug Facts

Active ingredients	Purpose
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local anesthetic

Uses ▪ For the temporary relief of anorectal itching, burning and discomfort associated with hemorrhoids, anorectal disorders, inflamed hemorrhoidal tissues, or piles.

Warnings

For external use only

Ask a doctor before use if you have ▪ heart disease ▪ high blood pressure ▪ thyroid disease ▪ diabetes ▪ difficulty urinating due to enlarged prostate gland.

Ask a doctor or pharmacist before use if you are ▪ 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 this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if ▪ rectal bleeding occurs ▪ an allergic reaction occurs ▪ the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase ▪ condition worsens or does not improve within 7 days.

Keep out of reach of children. If swallowed, get medical help or contact a

Información del Medicamento

Ingredientes Activos	Propósito
Fenilefrina HCl 0.25%	Vasoconstrictor
Pramoxina HCl 1%	Anestésico local

Usos ▪ Para el alivio temporal de comezón anorectal, ardor y molestias asociadas con hemorroides y afecciones anorectales, tejido hemorroidal inflamado o hemorroides.

Advertencias

Solo para uso externo

Antes de usarse consulte a su médico si ud. padece ▪ enfermedad del corazón ▪ presión alta ▪ enfermedad de la tiroides ▪ diabetes ▪ dificultad para orinar debido al agrandamiento de la próstata.

Pregúntele a su médico o farmacéutico antes de usar si usted está ▪ tomando un medicamento recetado para la hipertensión arterial o la depresión.

Durante el uso de este producto ▪ no exceda la dosis 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.

Suspenda el uso y consulte a su médico si ▪ aparece sangrado rectal

NIKZON HEMORRHOIDAL

phenylephrine hydrochloride and pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50066-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PANTHENOL (UNII: WV9CM0O67Z)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-001-01	1 in 1 BOX	06/19/2019	
1		25 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	12/01/2013	

Labeler - Genoma Lab USA Inc (832323534)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(50066-001)

Revised: 11/2021 Genoma Lab USA Inc