

GIGI ANESTHETIC NUMBING - lidocaine aerosol
220 LABORATORIES 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.

NUMBING SPRAY CONTAINER

ACTIVE INGREDIENT - LIDOCAINE 4%

PURPOSE - NUMBING

Uses: Lidocaine is a topical anesthetic that penetrates the surface of the skin, numbing the area to be epilated within minutes.

Warnings: For external use only. Avoid spraying in eyes. Do not spray directly on face. Discontinue use if irritation occurs. If accidentally ingested, seek medical assistance immediately. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

FLAMMABLE. KEEP AWAY FROM HEAT AND FLAME. KEEP OUT OF REACH OF CHILDREN.

Directions - Before waxing large areas (legs, backs, arms, underarms and bikini areas) spray directly onto the skin. Do not spray near eyes or mouth. For waxing any part of the face, spray onto cloth, cotton ball or swab. Wait approximately 2-3 minutes for skin to numb, then proceed with waxing service. After waxing, spray or apply with cloth, cotton ball or swab for added comfort.

GiGi Anesthetic Numbing Spray
for sensitive skin

Temporarily numbs the skin taking the sting out of waxing while soothing the skin.

Active ingredient Lidocaine 4% **Purpose** Numbing

Use Lidocaine 4% a topical anesthetic that numbs the surface of the skin, numbing the area to be epilated within minutes.

Warnings: For external use only. Avoid spraying in eyes. Do not spray directly on face. Discontinue use if irritation occurs. If accidentally ingested, seek medical assistance immediately. Contents under pressure. **DO NOT** puncture or incise. **DO NOT** store at temperature above 120°F. **FLAMMABLE. KEEP AWAY FROM HEAT AND FLAME. KEEP OUT OF REACH OF CHILDREN.**

DIRECTIONS: Before using large areas (legs, back, arms, underarms & other areas) spray directly onto the skin. Do not spray near eyes or mouth. For weeding any part of the face, spray onto cloth, cotton ball or swab. Wait approximately 2-3 minutes for skin to numb, then proceed with weeding service. After weeding, spray or apply with cloth, cotton ball or swab for added comfort.

Other ingredients: Isododecane, Isobutane, Alcohol Denat., Thymol, Eugenol, Octyl-5, Caprylic/Capric Triglyceride, Fragrance (Parfum), Amyl Citrate, Benzyl Alcohol, Benzyl Benzoate, Benzyl Salicylate, Limonene, Citronellol, Hydroxypropylmethylcellulose, Methyl Propylolamine, Hydroxyacetophenone, 3-Cyclohexene Carboxaldehyde.

448015

Net wt 0.72oz (20.5g) / 2.5 fl.oz (73.7ml)
 Contains 100% Lidocaine HCl
 Lidocaine HCl 4% (20.5g) / 73.7ml
 Contains 100% Lidocaine HCl
 Lidocaine HCl 4% (73.7ml) / 20.5g
 BE 137 - www.digitals.com

15-0857

Ingredient Actif Lidocaïne 4% **But** Engourdissement

Utilisation: La lidocaïne est un anesthésique utilisé activement. Il pénètre à la surface de la peau et engourdit la zone à épiler en quelques minutes.

AVERTISSEMENTS: Usage externe uniquement. Éviter de vaporiser dans les yeux. Ne pas vaporiser directement sur le visage. Interrompre l'utilisation en cas d'irritation. En cas d'ingestion accidentelle, avoir immédiatement recours à une assistance médicale. Contenu sous pression. **NE PAS** poncer, ni inciser. **NE PAS** stocker à une température supérieure à 120°F / 50°C. **INFLAMMABLE. TENIR ÉLOIGNÉ DES SOURCES DE CHALEUR ET DES FLAMMES. TENIR HORS DE LA PORTEE DES ENFANTS.**

INSTRUCTIONS: Avant d'épiler des zones étendues (jambes, dos, bras, aisselles et maillot), vaporiser directement sur la peau. Ne pas vaporiser près des yeux ou de la bouche. Pour épiler une partie du visage, vaporiser sur une éponge, un disque à démaquiller ou un tampon. Attendez environ 2-3 minutes pour que la peau soit engourdie, puis procédez à l'épilation à la cire. Après l'épilation à la cire, vaporiser ou appliquer avec une éponge, un disque à démaquiller ou un tampon pour un meilleur confort.

Autres ingrédients: Isododecane, Isobutane, Alcool (Denat.), Thymol, Eugenol, Acide Caprylique/Trioléine Caprique, Octyl-5, Fragrance (Parfum), Amyl Citrate, Alcool Benzyle, Benzoate de Benzyle, Salicylate de Benzyle, Limonène, Citronelle, Hydroxypropylméthylcellulose, Méthyle Propylolamine, Linalol, Carboxaldehyde Cyclohexane, Hydroxyacétophénone.

PHOTO COPY PROHIBITED

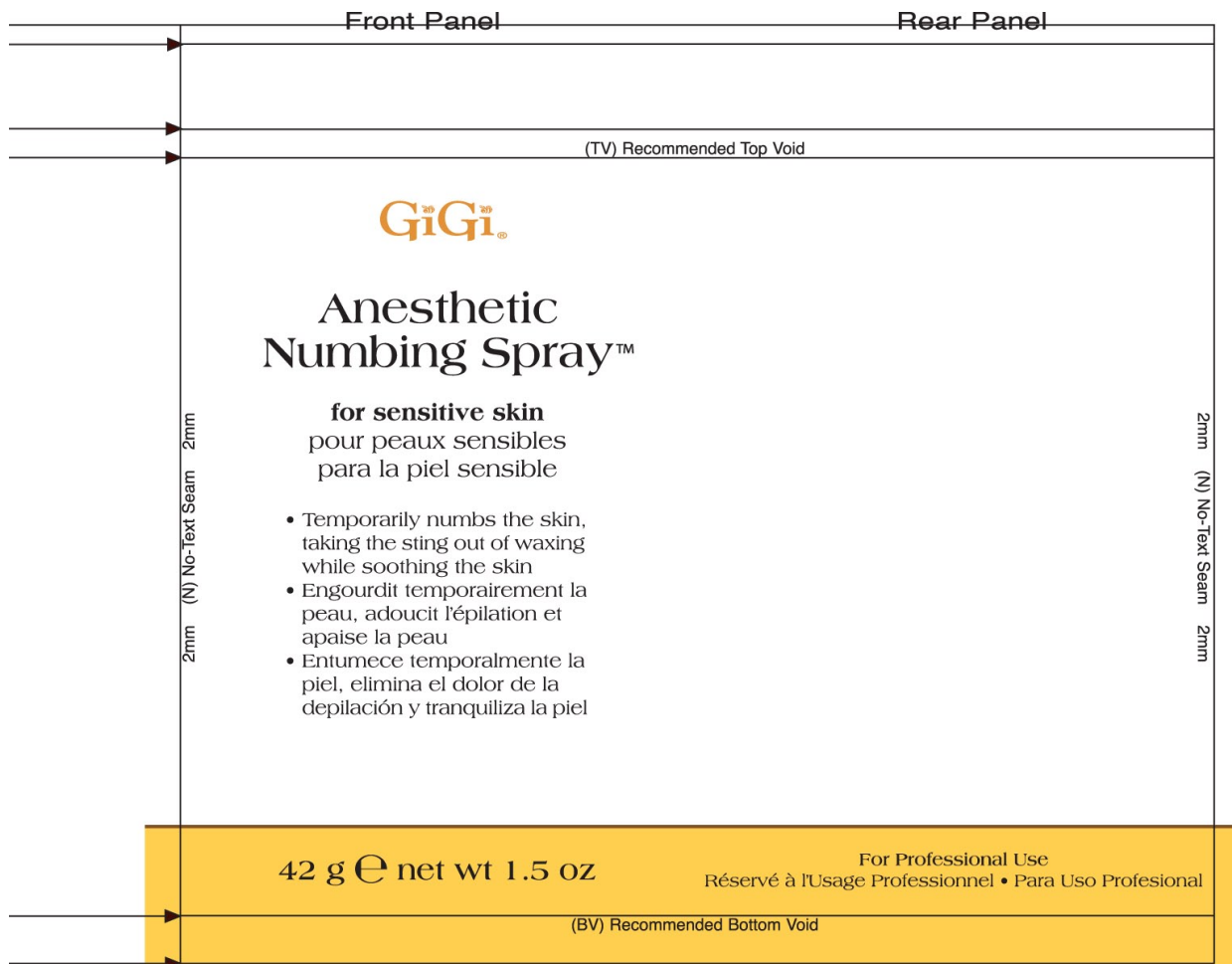
Ingrediente Activo Lidocaína al 4% **Objetivo** Entumecimiento

Uso: La lidocaína es un anestésico tópico que penetra en la superficie de la piel entumeciendo el área a depilar dentro del lapso de de pocos minutos.

ATENCIÓN: Sólo para uso externo. Evite pulverizarlo en los ojos. No pulverice directamente en la cara. Interrompa el uso si aparece una irritación. Si se ingiere accidentalmente, llame al médico. El contenido es helio bajo presión. NO lo pliegues ni quemes. NO lo conserves a una temperatura superior a 120°F / 50°C. **INFLAMMABLE. MANTÉNGASE ALEJADO DE CALOR Y DEL FUEGO. MANTÉNLO FUERA DEL ALCANCE DE LOS NIÑOS.**

INSTRUCCIONES: Antes de remover áreas grandes (piernas, espalda, brazos, antebrazos y entorno del bikini) pulveriza directamente a la piel. No pulverice cerca de los ojos ni la boca. Si enceras cualquier parte de la cara, pulveriza en un paño, una toalla de algodón o una gasa. Espere unos 2 a 3 minutos para que la piel se entumezca, a continuación realiza el encoado. Después del encoado, pulveriza o aplica con un paño, una toalla de algodón o gasa para tener un confort adicional.

Otros ingredientes: Isododecano, Alcohol (Denaturado), Timol, Eugenol, Triglicérido Caprílico/Caprico, Octil-5, Fragancia (Parfum), Amil Citrato, Benzil Alcohol, Benzil Benzoato, Benzil Salicilato, Limoneno, Citronelol, Hidroxipropilmetilcelulosa, Difencil Metilpropilamoni, Linalol, Hidroxiacetofenoni, 3-Ciclohexeno Carboxaldeido.



GIGI ANESTHETIC NUMBING

lidocaine aerosol

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57367-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49TP611)	
THYMOL (UNII: 3J50XA376E)	
EUGENOL (UNII: 3T8H1794QW)	
ALCOHOL (UNII: 3K9958V90M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OLETH-5 (UNII: 1GH33785AY)	
ISODODECANE (UNII: A8289P68Y2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57367-001-01	42 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/27/1997	

Labeler - 220 LABORATORIES INC (783247950)

Registrant - 220 LABORATORIES INC (783247950)

Establishment

Name	Address	ID/FEI	Business Operations
220 LABORATORIES INC		783247950	manufacture

Revised: 5/2010

220 LABORATORIES INC