

XESSO STRAWBERRY REAR COMFORT GLIDE 4% LIDOCAINE- lidocaine gel Premium Natural Cosmetics 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.

Xesso Strawberry Rear Comfort Glide 4% Lidocaine

Active Ingredient

Lidocaine 4%

Ask a doctor section

As with any drug, consult a health care professional if you are pregnant or nursing. Ask a health care professional before using this product.

Purpose

Anorectal

Use

For temporary relief of pain, soreness, or burning in the perianal area.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, seek medical help or call a Poison Control Center right away.

Stop Use

Certain persons can develop allergic reactions to ingredients in this product. If the symptoms being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

Directions

- Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly by patting or blotting with an appropriate cleansing pad. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Apply externally to the affected area up to 6 times daily.

Warnings

Warnings:

- For external use only. Do not use this product with a mechanical device.
- Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor.
- Do not exceed the daily recommended dosage.
- Do not apply onto cracked or broken skin.
- In case of any bleeding, discontinue use and consult a doctor.

Other information

Other Information:

- Store at room temperature 20 - 25°C (68 - 77°F).
- Do not use if tamper evident seal on the outside of the container is broken or missing.

Inactive Ingredients

Inactive Ingredients: Carboxymethylcellulose Sodium, Diazolidinyl urea, Glycerin, Isopentyldiol, Methylparaben, Propylparaben, Water, Natural Flavor.

Principle Display Panel



4% lidocaine for enhanced comfort
Smooth silky glide
Easy to clean

SCENTED REAR COMFORT

Glide

SLIPPERY & MILD NUMBING

strawberry

Thick
Water-based Formula
Natural Flavor
PEG Free & Oil-Free



Natural Flavor



Lightweight



Mild Numbing



Non-Staining

Drug Facts:

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Lidocaine 4%	Anorectal

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MADE IN THE USA



Manufactured In an USA facility For:
Premium Natural Cosmetics INC.
Thousand Oaks, CA 91320
Product Made in the U.S.A.

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8.3 fl. oz. | 245 mL e

XESSO STRAWBERRY REAR COMFORT GLIDE 4% LIDOCAINE

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81777-105
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4.625 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	0.5 g in 100 mL
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.5 g in 100 mL

GLYCERIN (UNII: PDC6A3C0OX)	54.3 g in 100 mL
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.3 g in 100 mL
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	0.7 g in 100 mL
ISOPENTYLDIOL (UNII: 19NOL5474Q)	0.4 g in 100 mL
WATER (UNII: 059QF0KO0R)	38.76 g in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81777-105-01	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/13/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	12/13/2022	

Labeler - Premium Natural Cosmetics Inc (051403646)

Revised: 10/2023

Premium Natural Cosmetics Inc