

XESSO REAR COMFORT GLIDE- 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 Rear Comfort Glide 2% Lidocaine

Active Ingredient

Lidocaine 2%

Ask a doctor

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. If case of accidental overdose, seek medical help or call a Poison Control Center right away.

Sop Use

Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, 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 are up to 6 times daily.

Warning

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

Store at room temperature 20 - 25 C (68 F - 77F)

Inactive Ingredients

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

Principal Display Panel



8.0 fl. oz. Bullet Bottle Private Label

XESSO REAR COMFORT GLIDE

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81777-104
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.35 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPENTYLDIOL (UNII: 19NOL5474Q)	0.4 g in 100 mL
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.3 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	54.3 g in 100 mL
METHYLPARABEN (UNII: A2I8C7HI9T)	0.5 g in 100 mL

PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.5 g in 100 mL
WATER (UNII: 059QF0KO0R)	41.25 g in 100 mL
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.7 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81777-104-01	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	11/10/2022	

Labeler - PREMIUM NATURAL COSMETICS INC (051403646)

Revised: 10/2023

PREMIUM NATURAL COSMETICS INC