

## **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.*

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## **Xesso Rear Comfort Glide**

### **Active Ingredient**

Lidocaine 4%

### **Ask a doctor section**

Ask a health professional before using this product.

### **Do not Use**

- Do not exceed the daily recommended dosage.
- Do not apply onto cracked or broken skin.
- In case of bleeding, discontinue use and consult a doctor.

### **Keep out of reach of children**

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

### **Purpose Section**

Anorectal

### **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.

In case of any bleeding, discontinue use and consult a doctor.

### **Pregnancy or Breast Feeding Section**

As with any drug, consult a health care professional if you are pregnant or nursing.

### **Inactive Ingredients**

Carboxymethylcellulose sodium, diazolidinyl urea, glycerin, isopentyldiol, methylparaben,

propylparaben, water

## 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.

## Use

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

## 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.
- 
- **Keep out of reach of children.** In case of accidental overdose, seek medical help or call a Poison Control Center right away.
  - As with any drug, consult a health care professional if you are pregnant or nursing. Ask a health care professional before using this product.

## Other Information

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

Xesso Black

Rear Comfort Glide

Slippery and Mild Numbing

Thick, Water-Based Formula

PEG-Free and Oil-Free

8.3 fl oz | 245 mL

NDC Code: 81777-101-01



# REAR COMFORT Glide

SLIPPERY & MILD NUMBING

THICK, WATER-BASED FORMULA

PEG-Free & Oil-Free

8.3 fl. oz. | 245 mL e



Lightweight



Mild Numbing



Non-Staining



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

### Drug Facts:

Active Ingredient	Purpose
Lidocaine 4%	Anorectal

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### Directions:

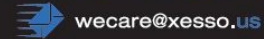
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- Store at room temperature 20 - 25°C (68 - 77°F).
- Do not use if tamper evident seal on the outside of the container is broken or missing.

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

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.

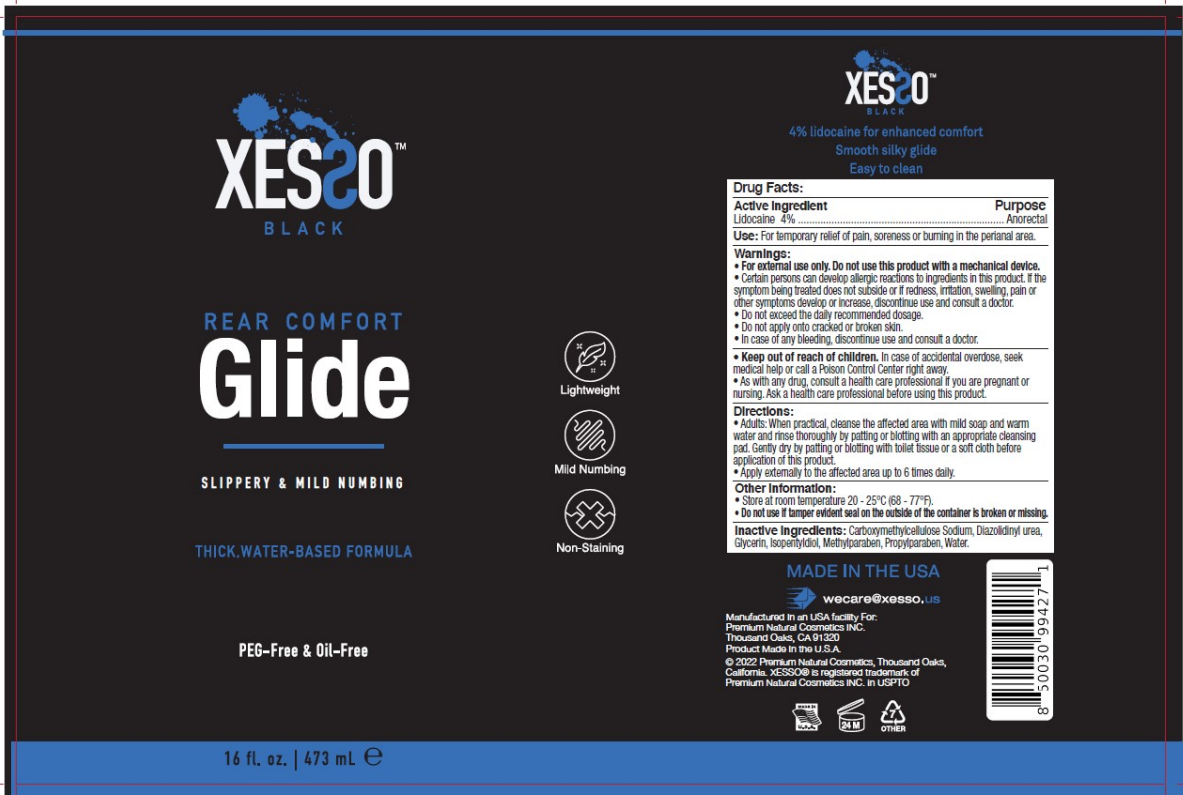
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ITEM PRD01003

LAB01003

Rear Comfort Glide 16 fl oz



**4 fl oz Label PDP**



**XESSO REAR COMFORT GLIDE**

lidocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81777-101
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4.625 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	46.282 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	46.911 g in 100 mL
<b>ISOPENTYLDIOL</b> (UNII: 19NOL5474Q)	0.864 g in 100 mL
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	0.05 g in 100 mL
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	0.05 g in 100 mL
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	0.3 g in 100 mL
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	0.454 g in 100 mL

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:81777-101-01	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2021	
2	NDC:81777-101-03	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/05/2022	
3	NDC:81777-101-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2021	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	M015	06/01/2021	

**Labeler** - Premium Natural Cosmetics Inc (051403646)

Revised: 10/2023

Premium Natural Cosmetics Inc