## BOTTOMS UP- lidocaine liquid WSM Investment LLC dba Topco Sales

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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Lidocaine 5%

Anorectal

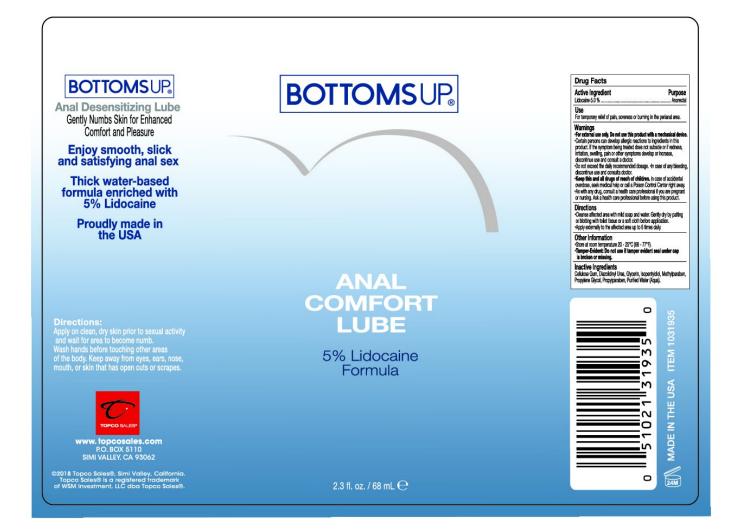
For temporary relief of pain, soreness, or burning in the perianal area.

- **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
- In case of any bleeding, discontinue use and consult a doctor.
- Avoid contact with eyes, in case of eye contact, flush with water.
- **Keep this and all drugs out of reach of children**. If swallowed, 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.
- Cleanse affected area with mild soap and water.
- Gently dry by patting or blotting with soft cloth or tissue before application.
- Apply externally to the affected area up to 6 times daily.
- Store at room temperature 20-25°C (68-77°F).
- Tamper-Evident: Do not use if tamper evident seal under cap is broken or missing.

Cellulose Gum, Diazolidinyl Urea, Glycerin, Isopentyldiol, Methylparaben, Propylene Glycol, Propylparaben, Purified Water (Aqua).



<b>BOTTOMS UP</b>									
lidocaine liquid									
-									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:69797-103					
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
Ingredient Name			<b>Basis of Strength</b>		Strength				
LIDO CAINE (UNII: 98PI200987) (LIDO	CAINE - UNII:98PI200987)		LIDOCAINE		3.4 g in 68 mL				
Inactive Ingredients									
	Ingredient Name				Strength				

PR	OPYLENE GLYCO	L (UNII: 6DC9Q167V3)				
ISC	<b>DPENTYLDIOL</b> (UN	NII: 19NOL5474Q)				
CA	RBOXYMETHYLC	ELLULOSE CALCIUM (UNII: UTY7PDF93L)				
DI	AZOLIDINYL UREA	(UNII: H5RIZ3MPW4)				
ME	ETHYLPARABEN (U	NII: A2I8C7HI9T)				
WA	ATER (UNII: 059QF0	KO0R)				
PR	OPYLPARABEN (U	NII: Z8IX2SC1OH)				
GLYCERIN (UNII: PDC6A3C0OX)						
	ickaging Item Code	Package Description	Marketing Start Date	Marketing End Date		
#	Item Code	<b>Package Description</b> 68 mL in 1 BOTTLE: Type 0: Not a Combination Product	Marketing Start Date	Marketing End Date		
# 1 1	<b>Item Code</b> NDC:69797-103-01	<b>Package Description</b> 68 mL in 1 BOTTLE; Type 0: Not a Combination Product 186 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2017	Marketing End Date		
# 1 1 1 2 1	Item Code NDC:69797-103-01 NDC:69797-103-02	68 mL in 1 BOTTLE; Type 0: Not a Combination Product 186 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2017	Marketing End Date		
# 1 I 2 I M	Item Code NDC:69797-103-01 NDC:69797-103-02	68 mL in 1 BOTTLE; Type 0: Not a Combination Product 186 mL in 1 BOTTLE; Type 0: Not a Combination Product <b>Drmation</b>	12/15/2017 12/15/2017			
# 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Item Code NDC:69797-103-01 NDC:69797-103-02	<ul> <li>68 mL in 1 BOTTLE; Type 0: Not a Combination Product</li> <li>186 mL in 1 BOTTLE; Type 0: Not a Combination Product</li> <li>Drmation</li> <li>Application Number or Monograph Citation</li> </ul>	12/15/2017	Marketing End Date		

## Labeler - WSM Investment LLC dba Topco Sales (040346439)

## Establishment

Name	Address	ID/FEI	Business Operations
WSM Investment LLC. Topco Sales		040346439	manufacture(69797-103)

Revised: 12/2017

WSM Investment LLC dba Topco Sales