

**REG- lidocaine hydrochloride gel**  
**TG Ventureprises LLC**

*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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**Numb Gel 5%**

**Numb Gel 5.0%**

<b>REG</b>			
lidocaine hydrochloride gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73663-001
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>	<b>Strength</b>	
	ALCOHOL (UNII: 3K9958V90M)	4 g in 100 g	
	CUCUMBER JUICE (UNII: 61845009SP)	0.1 g in 100 g	
	CARBOMER 940 (UNII: 4Q93RCW27E)	2 g in 100 g	
	GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g	
	CAFFEINE (UNII: 3G6A5W338E)	0.25 g in 100 g	
	1,3-PROPANEDIOL BIS(4-AMINO BENZOATE) (UNII: 8860R9ORQR)	5 g in 100 g	
	ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.2 g in 100 g	
<b>Product Characteristics</b>			
<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73663-001-04	120 g in 1 JAR; Type 0: Not a Combination Product	10/01/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/01/2020	

**Labeler** - TG Ventureprises LLC (117373103)**Establishment**

Name	Address	ID/FEI	Business Operations
Debut Development LLC		079705544	manufacture(73663-001)

Revised: 7/2020

TG Ventureprises LLC