

**MYDERM NUMBING ROLL-ON- inspec solutions llc cream  
Inspec Solutions 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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**myDerm Numbing Roll-On 5% Lidocaine**

Active Ingredient

Lidocaine HCl 5%

**Uses** Helps relieve anorectal symptoms (pain, soreness, burning, itching). Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders.

**Warnings** For external use only

**When using this product** • avoid contact with the eyes or mucous membranes.

**Stop use and ask doctor if** • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur again within a few days. Do not use if pregnant or breast-feeding.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

Do not use if pregnant or breast-feeding.

**Directions** • Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. • Children under 2

**Inactive Ingredients** Crosspolymer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol,

C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl

Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicyetyl

Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl

Stearate, Phenoxyethanol, SD Alcohol 40, Steareth-21 , Water.



inspec solutions llc cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72667-058
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETETH-20 PHOSPHATE</b> (UNII: 921FTA1500)	
<b>DIHEXADECYL PHOSPHATE</b> (UNII: 2V6E5WN99N)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER</b> (UNII: 4ZK9VP326R)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DEHYDRATED ALCOHOL</b> (UNII: 3K9958V90M)	
<b>STARETH-21</b> (UNII: 53J3F32P58)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-058-01	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/02/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/02/2023	

**Labeler** - Inspec Solutions LLC. (081030372)

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## Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(72667-058)

Revised: 1/2023

Inspec Solutions LLC.