

**SONACAINE TOPICAL ANESTHETIC WITH MENTHOL- lidocaine gel**  
**Filltech USA, LLC**

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**Sonacaine Topical Anesthetic Gel With Menthol**

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**Drug Facts**

**Active Ingredients**

Lidocaine 4%

**Purpose**

Topical Anesthetic

**Uses:**

temporary relieves pain and itching due to:

- minor cuts
- sunburn
- minor scrapes
- minor burns
- insect bites
- minor skin irritations

**Warnings:**

For external use only.

**Keep out of reach of children**

**Directions:**

Adults and children 2 years of age or older: Apply to affected area not more than 3 to 4 times daily.

**Other Ingredients:**

Aloe Barbadensis Leaf Juice, Calendula Officinalis Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Chamomilla Recutita (Matricaria) Flower Extract, Diazolidinyl Urea, Disodium EDTA, Glycerin, Menthol, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, SD Alcohol 40-2, Symphytum Officinale (Comfrey) Leaf Extract, Triethanolamine

**Sonacaine Topical Anesthetic Gel With Menthol 2oz/60g (62221-935-02)**

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**WITH MENTHOL**

**sōnacaine®**

TOPICAL ANESTHETIC GEL

2 oz. (60 g)

Manufactured by FillTech USA, Rockwell, NC 28138

[www.filltechusa.com](http://www.filltechusa.com)

# SONACAINE TOPICAL ANESTHETIC WITH MENTHOL

lidocaine gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62221-935
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
COMFREY LEAF (UNII: DG4F8T839X)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62221-935-02	60 g in 1 BOTTLE; Type 0: Not a Combination Product	05/02/2012	

## 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 Drug	M017	05/02/2012	

**Labeler** - Filltech USA, LLC (926433855)

**Registrant** - Filltech USA, LLC (926433855)

**Establishment**

Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		926433855	manufacture(62221-935)

Revised: 11/2023

Filltech USA, LLC