

## **CARPAL COMFORT- benzyl alcohol, lidocaine hci cream** **Comfort Lab, LP**

*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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### **Carpal Comfort**

Benzyl Alcohol, Lidocaine HCl

### **INDICATIONS**

For temporary relief of pain.

- For external use only
- Avoid contact with eyes

Keep out of reach of children. If swallowed, consult physician.

If pregnant or breast feeding, contact physician prior to use.

If symptoms persist more than seven days, discontinue use and consult physician.

### **ADDITIONAL INFORMATION**

Store at room temperature.

Questions or comments? [www.carpalcomfort.com](http://www.carpalcomfort.com)

Topical Anesthetic

LIDOCAINE HYDROCHLORIDE

BENZYL ALCOHOL

POLYSORBATE 20

PROPYLENE GLYCOL

BOSWELLIA SERRATA RESIN OIL

ILEX PARAGUARIENSIS LEAF

MAGNESIUM SULFATE, UNSPECIFIED

SPEARMINT OIL

ALCOHOL

TRIETHANOLAMINE SULFATE

XANTHAN GUM

WATER

PHENOXYETHANOL

ARNICA MONTANA FLOWER WATER

DIMETHYL SULFONE

CARBOMER 980

ETHOXYDIGLYCOL BEHENATE

Adults and children two-years of age and older:

Apply to affected area not more than three to four times a day.

Children under two years of age:

Consult a physician

LIDOCAINE HYDROCHLORIDE

BENZYL ALCOHOL

POLYSORBATE 20

PROPYLENE GLYCOL

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ETHOXYDIGLYCOL BEHENATE



CARPALCOMFORT™

Soothes and Relieves  
Hand and Wrist Pain

Dr. Daniel Penello™

Hand and Wrist Surgeon

3 FL. OZ. (88mL)

Doctor Designed and Recommended

<b>DRUG FACTS:</b>	
<b>Active Ingredients:</b> Benzyl Alcohol Lidocaine HCl	10.00% Topical Anesthetic 1.00% Topical Anesthetic
<b>Indications:</b> For the temporary relief of pain.	
<b>Warnings:</b> • For external use only. • Avoid contact with eyes. • If symptoms persist for more than 3 days, discontinue use and consult physician. • <b>Keep out of reach of children.</b> If swallowed, consult physician. • Do not apply to wounds or damaged skin. • Do not bandage tightly. • If symptoms do not improve, consult your physician prior to use.	
<b>Directions:</b> • Adults and children 12 years of age or older: Apply to affected area 4-6 times daily. • Children under 12 years of age: consult a physician.	
<b>Additional Information:</b> Store at room temperature.	
<b>Other Ingredients:</b> Aqua (Distilled Water), Anise Hydrate Extract, Butyl Alcohol, Ethanol, Ethylhexylglycol, Ethylhexylglycol Olefin Polyether, Glycerin, Hydroxyethylcellulose, Methylparaben, Propylparaben, Potassium Hydroxide, Polyethylene Glycol 400, Polyethylene Glycol 600, Propylparaben, Stearic Acid, Triethylamine, Xanthan Gum.	
<b>Distributed By:</b> CarpalComfort, LLC, 9410 Highway 19, 33704.	<b>Best Before:</b>
<b>Questions or Comments?</b> <a href="http://www.CarpalComfort.com">www.CarpalComfort.com</a>	



## CARPAL COMFORT

benzyl alcohol, lidocaine hci cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73214-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	10 mg in 100 mL
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 mg in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ETHOXYDIGLYCOL BEHENATE</b> (UNII: N76ISC4ZZO)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>BOSWELLIA SERRATA RESIN OIL</b> (UNII: 5T1XCE6K8K)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>MAGNESIUM SULFATE, UNSPECIFIED</b> (UNII: DE08037SAB)	
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>TRIETHANOLAMINE SULFATE</b> (UNII: MV1V89M17O)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ARNICA MONTANA FLOWER WATER</b> (UNII: U7L2JP51PR)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73214-001-01	1 in 1 BOX	07/10/2019	
1		88 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2019	

**Labeler** - Comfort Lab, LP (117057860)