

**MUCINEX INSTA SOOTHE SORE THROAT WINTER FRESH- benzocaine and menthol, unspecified form spray**  
**RB Health (US) LLC**

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**Mucinex® INSTASOOTHE™ Sore Throat Winter Fresh**

## **Drug Facts**

### **Active Ingredients**

Benzocaine 5%

Menthol 2%

### **Purpose**

Oral Pain Reliever

### **Uses**

temporarily relieves occasional minor irritation and pain associated with

- sore throat
- sore mouth
- canker sores

### **Warnings**

**Methemoglobinemia warning:** Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

**Allergy alert:** Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other 'caine' anesthetics.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly.

### **Do not use**

- for teething
- in children under 6 years of age

**When using this product:**

do not exceed recommended dosage

**Stop use and ask a doctor or dentist if**

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**Adults and children 6 years of age and older:

- apply to affected area (one spray); gargle, swish around in the mouth, or allow to remain in place at least 1 minute then spit out. Use up to 4 times daily or as directed by a doctor or dentist. Children 6 to under 12 years of age **SUPERVISE USE**

Children under 6 years of age:

- do not use

**Other Information**

store at 20-25°C (68-77°F)

**Inactive Ingredients**

anhydrous citric acid, cetylpyridinium chloride, dibasic sodium phosphate, edetate disodium, flavor, hydrochloric acid\*, polyethylene glycol, propylene glycol, purified water, sodium hydroxide\*, sucralose

\*may contain this ingredient

**Questions?**

1-866-MUCINEX (1-866-682-4639)

You may also report side effects to this phone number.

Dist. by: RB Health (US)

Parsippany, NJ 07054-0224

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www.mucinex.com

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## Principle Display Panel

NDC: 72854-266-04

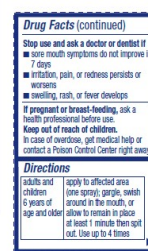
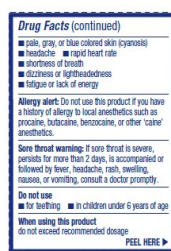
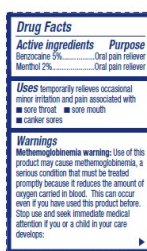
Mucinex® INSTASOOTHE™

Benzocaine 5.0mg oral pain reliever

Menthol 2.0mg oral pain reliever

- ✓ Numbs Pain Fast
- ✓ Maximum Cool

Product Label



# MUCINEX INSTA SOOTHE SORE THROAT WINTER FRESH

benzocaine and menthol, unspecified form spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72854-266
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 mL
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	2 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

## Product Characteristics

<b>Color</b>	yellow (clear to yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-266-04	115 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2023	

**Labeler** - RB Health (US) LLC (081049410)

Revised: 1/2024

RB Health (US) LLC