

MUCINEX INSTASOOTHE SORE THROAT PLUS PAIN RELIEF- benzocaine and menthol, unspecified form spray
RB Health (US) LLC

MUCINEX® INSTASOOTHE™
SORE THROAT PLUS PAIN RELIEF

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Benzocaine 7%	Oral pain reliever
Menthol 1%	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

Questions?

(1-866-682-4639) You may also report side effects to this phone number.

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224

Made in Canada

PRINCIPAL DISPLAY PANEL - 115 mL Bottle Label

NDC 72854-265-04
ALCOHOL-FREE

Mucinex®
INSTASOOTHE™

SORE THROAT
+ PAIN RELIEF

Benzocaine 7% | Oral Pain Reliever
Menthol 1% | Oral Pain Reliever

- Numbs Pain Fast
- Two Powerful
Pain Relievers

3.8 FL OZ (115 mL)
500 Doses
CHERRY
FLAVOR SPRAY

031121
3184012

NDC 72854-265-04

ALCOHOL-FREE



SORE THROAT + PAIN RELIEF

Benzocaine 7% | Oral Pain Reliever
Menthol 1% | Oral Pain Reliever

031121 3184012



- ✓ **Numbs Pain Fast**
- ✓ **Two Powerful Pain Relievers**

3.8 FL OZ (115 mL)

500 Doses

**CHERRY
FLAVOR SPRAY**

PEEL HERE FOR COMPLETE DRUG FACTS & Tamper evident. Do not use if printed tamper evident band is broken or missing.

Dist. by: RB Health (US)
Paramaribo, NJ 07654-0224
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Made in Canada
www.mucinex.com

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LOT: 110723
EXP: 11/23

Patents: www.reckitt.com/patents

Drug Facts

Active ingredients Purpose
Benzocaine 7% Oral pain reliever
Menthol 1% Oral pain reliever

Uses temporarily relieves occasional minor irritation and pain associated with
 ■ sore throat ■ sore mouth
 ■ other sores

Warnings
Metemoglobinemia 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:

Drug Facts (continued)

■ 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, lidocaine, 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 swelling ■ in children under 6 years of age
 When using this product do not exceed recommended dosage

PEEL HERE ▶

Drug Facts (continued)

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 apply to affected area (one spray), gargle, wash around in the mouth, or allow to remain in place at least 1 minute then spit out. Use up to 4 times.

Drug Facts (continued)

daily or as directed by a doctor or dentist. Children 6 to under 12 years of age **SUPERVISE USE.**
 Children under 6 do not use (5 years of age)

Other information
 ■ store at 20-25°C (68-77°F)

Inactive ingredients anhydrous citric acid, erythritol, hydroxyethylcellulose, dibasic sodium phosphate, edetate disodium, flavor, hydrochloric acid, polyethylene glycol, propylene glycol, purified water, sodium hydroxide*, sucrose
 *may contain this ingredient

Questions?
 1-866-MUCINEX (1-866-682-4630)

benzocaine and menthol, unspecified form spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-265
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7 g in 100 mL
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-265-04	115 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/2021	

