CEPACOL ULTRA SORE THROAT- benzocaine and glycerin spray
RB Health (US) 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.

Cēpacol®
ULTRA
SORE THROAT SPRAY

Drug Facts

Active ingredients	***Purpose***
Benzocaine 5%	Oral pain reliever
Glycerin 33%	Oral demulcent

Uses

for the temporary relief of

- occasional minor irritation, pain, sore mouth, and sore throat
- pain associated with canker sores
- minor discomfort and protection of irritated areas in sore mouth and sore throat

Warnings

Allergy alert

- Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or any 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.

Stop use and ask a doctor or dentist if sore mouth symptoms do not improve in 7 days

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

Keep this and all drugs out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not exceed recommended dosage.

Flammable. Keep away from fire, flame or heat.

When using this product

- do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor
- in rare cases, this product may cause a loss of sensation in the throat which is temporary and harmless
- to avoid swallowing difficulties, avoid eating, chewing gum or sucking on lozenges for 20 minutes after using

Directions

- adults and children 6 years of age and older: spray into throat or onto affected area with only ONE spray per use. Allow to remain in place for at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor
- children 6 to under 12 years of age should be supervised in the use of this product
- children under 6 years of age: do not use

Other information

- tamper evident: product is sealed for your protection. Do not use if printed seal over nozzle is torn or missing.
- shake well before use
- store at room temperature 20-25°C (68-77°F)
- do not freeze

Inactive ingredients

acesulfame potassium, deionized water, flavors, neotame, polyoxyl-40 hydrogenated castor oil, povidone K90, SD alcohol 38B

Questions?

Call 1-888-963-3382

You may also report side effects to this phone number.

Distributed by: Reckitt Benckiser
Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 22.2 mL Bottle Carton

NDC 63824-780-75

Cēpacol®
ULTRA

SORE THROAT SPRAY

Benzocaine 5% | Oral Pain Reliever
Glycerin 33% | Oral Demulcent

Ultra1 SHOT for Pain Relief
Instant Acting • On-the-Go Comfort

100
Sprays

SUGAR FREE
cherry

0.75 FL OZ (22.2 mL)

Drug Facts

Active ingredients — **Purpose**
Benzocaine 5% ..... Oral pain reliever
Glycerin 33% ..... Oral demulcent

Uses for the temporary relief of
- occasional minor irritation, pain, sore mouth, and sore throat
- pain associated with canker sores
- minor discomfort and protection of irritated areas in sore mouth and sore throat

Warnings

Allergy alert - Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or any 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.

Stop use and ask a doctor or dentist if sore mouth symptoms do not improve in 7 days

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

Keep this and all drugs out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not exceed recommended dosage.

Flammable. Keep away from fire, flame or heat.

When using this product
- do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor
- in rare cases, this product may cause a loss of sensation in the throat which is temporary and harmless
- to avoid swallowing difficulties, avoid eating, chewing gum or sucking on lozenges for 20 minutes after using

Directions
- adults and children 6 years of age and older: spray into throat or onto affected area with only ONE spray per use. Allow to remain in place for at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor
- children 6 to under 12 years of age should be supervised in the use of this product
- children under 6 years of age: do not use ▶

Drug Facts (continued)

Other Information
- tamper evident: product is sealed for your protection. Do not use if printed seal over nozzle is torn or missing.
- shake well before use
- store at room temperature 20-25°C (68-77°F)
- do not freeze

Inactive ingredients
acesulfame potassium, deionized water, flavors, neotame, polyoxyl-40 hydrogenated castor oil, povidone K90, SD alcohol 38B

Questions? Call 1-888-963-3382
You may also report side effects to this phone number.

For instant acting on-the-go sore throat pain relief, also try Cēpacol® lozenges.
Available in Cherry, Honey Lemon, Sugar Free Cherry, and Mixed Berry flavors.

3-63824-78075-7

NDC 63824-780-75

Cēpacol® ULTRA

SORE THROAT SPRAY

Benzocaine 5% | Oral Pain Reliever
Glycerin 33% | Oral Demulcent

Ultra 1 SHOT for Pain Relief

Instant Acting • On-the-Go Comfort

0.75 FL OZ (22.2 mL)

Cēpacol® ULTRA
SORE THROAT SPRAY
Benzocaine 5% | Oral Pain Reliever
Glycerin 33% | Oral Demulcent

Spray Guard Instructions

To remove guard, gently pull from nozzle end.

After use, push guard back over nozzle until it snaps on.

www.cepacol.com

Reckitt Benckiser

011812
0380897

Dist. by: Reckitt Benckiser
Parsippany, NJ 07054-0224 ©2012 RB

CEPACOL ULTRA SORE THROAT
benzocaine and glycerin spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-780
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	5 g in 100 mL
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	33 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
WATER (UNII: 059QF0KO0R)	
NEOTAME (UNII: VJ597D52EX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POVIDONE K90 (UNII: RDH86HJV5Z)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63824-780-75	1 in 1 CARTON	05/03/2011	
1		22.2 mL in 1 BOTTLE; 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	part356	05/03/2011	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2018 RB Health (US) LLC