

**CEPACOL SORE THROAT- dyclonine hydrochloride and glycerin liquid
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®
SORE THROAT SPRAY**

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Dyclonine Hydrochloride 0.1%	Oral pain reliever
Glycerin 33%	Oral demulcent

Uses

for 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

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 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.

When using this producttry to avoid swallowing spray.

Directions

- adults and children 4 years of age and older: Spray 4 times into throat or affected area. Gargle, swish around or allow to remain in place at least 1 minute and then spit out. Repeat up to 4 times daily or as directed by a dentist or doctor. Children 4 to under 12 years of age should be supervised in the use of this product.

- children under 4 years of age: do not use

Other information

- store at room temperature 20-25°C (68-77°F)
- do not freeze

Inactive ingredients

cetylpyridinium chloride, D&C red #33, deionized water, FD&C yellow #6, flavor, menthol, phosphoric acid, poloxamer 338, potassium sorbate, sodium phosphate dibasic, sorbitol

Questions?

1-888-963-3382

You may also report side effects to this phone number.

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

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 63824-781-74

Cēpacol[®]

SORE THROAT SPRAY

Dyclonine HCl 0.1% • Oral Pain Reliever
Glycerin 33% • Oral Demulcent

Fast Sore Throat Relief

- Instant Acting
- Coats & Soothes

4 FL OZ (118 mL)

SUGAR FREE
cherry

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TAMPER EVIDENT: Do not use if printed seal over cap is torn or missing.

Contains FD&C Yellow #6

www.cepacol.com

Dist. by: Reckitt Benckiser 0341252
Parsippany, NJ 07054-0224 ©RB 2011 051911

PEEL BACK FOR ADDITIONAL INFORMATION ▶

Drug Facts (continued)

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Label Patent
#8,752,431

CEPACOL SORE THROAT

dyclonine hydrochloride and glycerin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-781
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DYCLONINE HYDROCHLORIDE (UNII: ZEC193879Q) (DYCLONINE - UNII:078A24Q300)	DYCLONINE HYDROCHLORIDE	0.1 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	33 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM45K49P)	
D&C RED NO. 33 (UNII: 9DBA05BB0L)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLOXAMER 338 (UNII: F75JV2T505)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-781-74	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2011	09/01/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/20/2011	09/01/2024

Labeler - RB Health (US) LLC (081049410)

Revised: 9/2023

RB Health (US) LLC