

CEPASTAT EXTRA STRENGTH- phenol lozenge
Insight Pharmaceuticals

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.

CĒPASTAT®
ORAL ANESTHETIC WITH PHENOL

Drug Facts

Active ingredient (per lozenge)

Phenol 29 mg

Purpose

Oral Anesthetic

Uses

temporarily relieves

- minor sore throat pain
- sore mouth
- minor mouth irritation
- pain associated with canker sores

Warnings

When using this product

- Do not use more than directed.

Stop use and ask a doctor if

- sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea or vomiting
- sore mouth symptoms last more than 7 days, or irritation, pain or redness continues or worsens

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

- dissolve a lozenge slowly in mouth

adults and children 12 years and older	take up to 2 lozenges every 2 hours as needed
children 6 to under 12 years	take up to 1 lozenge every 2 hours; not

children 6 to under 12 years	more than 10 lozenges in 24 hours
children under 6 years	ask a doctor

Other Information

Store at room temperature, below 86°F (30°C). Protect contents from humidity.

Inactive ingredients

Antifoam Emulsion, Caramel, Eucalyptus Oil, Gum Crystal, Menthol, and Sorbitol.

QUESTIONS?

Call 1-800-344-7239 or visit our website at www.insightpharma.com

Distributed by: **INSIGHT Pharmaceuticals Corp.**
Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 18 Lozenges carton

MENTHOL EUCALYPTUS FLAVOR

CĒPASTAT[®]

ORAL ANESTHETIC WITH PHENOL

FAST ACTING

SORE THROAT RELIEF

EXTRA STRENGTH*

18 LOZENGES

SUGAR FREE



CEPASTAT EXTRA STRENGTH

phenol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-219
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Phenol (UNII: 339NCG44TV) (Phenol - UNII:339NCG44TV)		Phenol	29 mg	
Inactive Ingredients				
Ingredient Name		Strength		
Caramel (UNII: T9D99G2B1R)				
Eucalyptus Oil (UNII: 2R04ONI662)				
Menthol (UNII: L7T10EIP3A)				
Sorbitol (UNII: 506T60A25R)				
Product Characteristics				
Color	BROWN (transparent)	Score	no score	
Shape	ROUND	Size	19mm	
Flavor	MENTHOL	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-219-18	18 in 1 BOX		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	07/07/2009		

Labeler - Insight Pharmaceuticals (176792315)

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