

**CEPASTAT SORE THROAT AND COUGH- benzocaine, dextromethorphan hbr,
menthol lozenge**

Insight Pharmaceuticals 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.

Cepasat Sore Throat and Cough

Tamper Evident: Do not use if blister package with “CĒPASTAT®” name has been disturbed or opened.

Drug Facts

Active Ingredients (in each lozenge)

Benzocaine 6 mg

Purpose

Oral Anesthetic/Analgesic

Active Ingredients (in each lozenge)

Dextromethorphan HBr 5 mg

Purpose

Cough Suppressant

Active Ingredients (in each lozenge)

Menthol 10 mg

Purpose

Oral Anesthetic/Analgesic

Uses

Temporarily relieves

- occasional minor irritation, pain, sore throat and sore mouth
- cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

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: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 6 years of age unless directed by a doctor.

Do not use

- this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health care professional before taking this product.
- this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

When using this product

do not exceed recommended dosage.

Stop use and ask a dentist or doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops
- cough persists for more than 1 week, tends to recur, or is accompanied by a high fever, rash, or persistent headache. These could be symptoms of a serious condition.

If pregnant or breast-feeding, ask a health care professional before use.**Keep out of reach of children.**

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

Directions

- **Adults and children over 12 years of age:** 2 lozenges every 4 hours – not to exceed 12 lozenges every 24 hours.
- **Children 6-12 years of age:** 1 lozenge every 4 hours – not to exceed 6 lozenges every 24 hours.
- **Children under 6 years of age:** consult a doctor.

Other information

- Store between 59°F and 86°F (15°C - 30°C).
- Protect from moisture.
- Check expiration date before using.

Inactive ingredients

acesulfame potassium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerine, hydrogenated starch hydrolysate, isomalt, soy lecithin, sucralose, water

Questions?

1-800-552-7932

PRINCIPAL DISPLAY PANEL

CĒPASTAT®

SORE THROAT & COUGH

Menthol/Benzocaine | Oral Anesthetic/Analgesic

Dextromethorphan HBr 5 mg | Cough Suppressant

FAST ACTING

SORE THROAT & COUGH RELIEF

18 LOZENGES
CHERRY
SUGAR FREE



CEPASTAT SORE THROAT AND COUGH

benzocaine, dextromethorphan hbr, menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-205
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg
BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5)	BENZOCAINE	6 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
ISOMALT (UNII: S870P55O2W)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	4mm
Flavor	CHERRY	Imprint Code	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-205-01	3 in 1 CARTON	10/01/2016	
1		6 in 1 BLISTER PACK; 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	10/01/2016	

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 3/2017

Insight Pharmaceuticals LLC