CEPASTAT SORE THROAT AND COUGH- benzocaine, dextromethorphan hbr, menthol lozenge Insight Pharmaceuticals LLC

Cepastat 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: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 6 mg | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 5 mg | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| ACESULFAME POTASSIUM (UNII: 230V73Q5G9) | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | |
| 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 | С |
| Contains | | | |

| F | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63736-205- 01 | 3 in 1 CARTON | 10/01/2016 | |
| 1 | L | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
| Category | Citation | Date | Date |

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 10/2024 Insight Pharmaceuticals LLC