Ceftibuten is a cephalosporin antibiotic, specifically a fourth-generation cephalosporin, marketed under the brand names CEDAX and SKYBACT.

### Pharmacokinetics

- **Absorption:** Ceftibuten is well absorbed after oral administration. The oral bioavailability of ceftibuten ranges from 33% to 51% in adult subjects. Absorption is not significantly affected by food. The peak plasma concentration occurs from 0.5 to 3 hours after a single oral dose.

- **Distribution:** Ceftibuten distributes into most tissues and body fluids, including the cerebrospinal fluid, bile, sputum, saliva, and semen. The drug is also present in breast milk.

- **Excretion:** Most of the administered dose of ceftibuten is excreted in the urine as unchanged drug. The drug has a half-life of approximately 2.5 hours.

### Clinical Uses

- **Upper Respiratory Infections:** Ceftibuten is effective in the treatment of community-acquired respiratory infections, such as acute bronchitis, sinusitis, otitis media, and pneumonia caused by susceptible bacteria.

- **Skin and Soft Tissue Infections:** It is also effective in the treatment of skin and soft tissue infections caused by susceptible gram-positive and gram-negative bacteria.

- **Urinary Tract Infections:** Ceftibuten is effective in the treatment of uncomplicated and complicated urinary tract infections caused by susceptible organisms.

### Microbiological Activity

- **Beta-Lactamase-Producing Strains:** Ceftibuten is active against a wide range of beta-lactamase-producing strains, including strains of *Staphylococcus aureus* and *Streptococcus pyogenes*.

- **Anaerobic Bacteria:** It is also active against anaerobic bacteria, including *Bacteroides* spp., *Clostridium* spp., and *Fusobacterium* spp.

### Susceptibility Testing

- **In Vitro Susceptibility:** Clinical and Laboratory Standards Institute (CLSI) breakpoints are used to determine susceptibility to ceftibuten. The MICs should be determined using a standardized method such as the agar dilution method or the broth microdilution method.

- **In Vivo Susceptibility:** Clinical response rates with ceftibuten may be lower in infections involving resistant bacteria. Therefore, it is important to consider the susceptibility of the organism before initiating treatment.

### Precautions

- **Renal Function:** Ceftibuten is primarily excreted renally. In patients with renal impairment, dosing adjustments may be necessary to avoid toxicity.

- **Liver Function:** There is limited information on the use of ceftibuten in patients with liver impairment. Use with caution and consider dose reduction.

### Adverse Reactions

- **Common:** Nausea, vomiting, diarrhea, abdominal pain, and headache.

- **Less Common:** Allergic reactions, including rashes, pruritus, and angioedema.

### Notes

- **Stability:** Ceftibuten is stable in most commonly used diluents and can be stored at room temperature for up to 24 hours before use.

- **Storage:** Store at room temperature and protect from light.

### Formulations

- **Capsules:** Each capsule contains 200 mg of ceftibuten. Suitable for oral use only.

- **Oral Suspension:** Cherry-flavored suspension containing 40 mg of ceftibuten per 5 mL. Suitable for oral use only.

### Dosage and Administration

- **Recommended Dose:** For most infections, the recommended dose is 200 mg twice daily for 3 or 4 days. Adjustments may be necessary in patients with renal impairment.

- **Special Populations:** Dosing adjustments may be necessary in elderly patients, patients with renal impairment, and patients with liver impairment.

- **Overdose:** Overdose symptoms may include nausea, vomiting, diarrhea, abdominal pain, and headache. Treatment includes supportive care and hydration.

### References


- United States Food and Drug Administration. *CeftibutenCapsules for Oral Suspension prescribing information*; 2020


### Further Information

- Additional information is available in the original articles and clinical guidelines referenced in the text.

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**NOTE:** The information provided is for educational purposes only and should not be used as a substitute for professional medical advice. Always consult a healthcare provider for specific medical advice.
Cefitube (ceftibuten capsules)

(Indication for oral suspension)

**FOR ORAL USE ONLY**

Cefitube is indicated for the treatment of documented or presumptive infections caused by bacteria listed in the **INDICATIONS AND USAGE** section of this labeling.

**DOSE AND ADMINISTRATION**

- **Adults**: Doses of 9 mg/kg once daily up to a maximum dose of 400 mg per day.
- **Pediatric patients weighing more than 45 kg**: Take the maximum daily dose of 400 mg Q24h.
- **Pediatric patients weighing 15–45 kg**: Take the maximum daily dose of 400 mg Q24h.
- **Pediatric patients weighing less than 15 kg**: Take 33 mg/kg Q24h.

**CONTRAINDICATIONS**

- Hypersensitivity to cephalosporins, penicillins, or other beta-lactam class antibiotics
- Patients with a previous history of anaphylaxis or angioedema due to cephalosporins or penicillins

**WARNINGS**

- U.K. and/or U.S. side effects
- Geriatric patients
- Pregnancy
- Lactation
- Nursing mothers

**ADVERSE REACTIONS**

- **Mild to Moderate**: Headache, skin rashes, urticaria, and pruritus.
- **Severe**: Anaphylaxis, angioedema, and anaphylactoid reactions.

**PRECAUTIONS**

- Pregnancy: Cefitube is not recommended for use in pregnant women due to potential risks.
- Lactation: Cefitube is not recommended for use in lactating women.
- Nursing Mothers: Cefitube is not recommended for use in nursing mothers.

**OVERDOSAGE**

- Overdosage of cephalosporins can cause cerebral irritation leading to convulsions.

**DRUG INTERACTIONS**

- Cefitube is not expected to have a clinically significant interaction with other drugs.

**LABORATORY TEST CHANGES**

- **Hematologic**: No significant changes in hematologic parameters were observed.
- **Chemical**: No significant changes in serum chemistry parameters were observed.
- **Urinalysis**: No significant changes in urine parameters were observed.

**STORAGE**

- Store at room temperature (20–25°C). Do not freeze.

**SUPPLIED**

- Cefitube capsules: 9 mg/kg or 400 mg/day PO (400 mg Q24h)
- Cefitube oral suspension: 90 mg/5 mL or 180 mg/5 mL

**REFERENCES**