

## **CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION**

### **CIPROFLOXACIN HCL and DEXAMETHASONE OTIC SUSPENSION (Ciprodex<sup>®</sup> – Alcon Canada)**

#### **Description:**

Ciprodex<sup>®</sup> is a combination of ciprofloxacin HCl and dexamethasone that is indicated for the local treatment of acute otitis media with otorrhea through tympanostomy tubes in pediatric patients aged six months and older and for acute otitis externa in pediatric and adult patients aged one year and older.

The review of ciprofloxacin HCl/dexamethasone (Ciprodex<sup>®</sup>) by the Common Drug Review was in response to a Request for Advice from the Advisory Committee on Pharmaceuticals which questioned if the CEDAC recommendation of January 26, 2005 that ciprofloxacin HCl/dexamethasone (Ciprodex<sup>®</sup>) not be listed, should be changed in light of the recent withdrawal from the market of otic ciprofloxacin HCl/hydrocortisone (Cipro HC<sup>®</sup>).

#### **Recommendation:**

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that ciprofloxacin HCl/dexamethasone (Ciprodex<sup>®</sup>) otic suspension be listed in patients with acute otitis media with otorrhea through tympanostomy tubes who require treatment and in patients with acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane.

#### **Reasons for the Recommendation:**

1. For patients with otitis externa, one randomized trial compared topical otic ciprofloxacin HCl/dexamethasone with neomycin, polymixin B and hydrocortisone otic suspension and found a slight advantage in favor of topical ciprofloxacin HCl/dexamethasone in symptoms on days three and eighteen, but not on day eight.
2. For patients with otitis media with tympanostomy tubes, available studies compare ciprofloxacin HCl/dexamethasone otic suspension with ciprofloxacin ophthalmic solution (Ciloxan<sup>®</sup>) and with ofloxacin otic solution. Compared to ciprofloxacin ophthalmic solution, the clinical cure rate was significantly higher with ciprofloxacin HCl/dexamethasone at day 3, but not at day 8 or 14. In a second trial, topical ciprofloxacin HCl/dexamethasone resulted in a slightly greater improvement in symptoms compared to ofloxacin otic solution, although the clinical importance of these differences is unclear.
3. Ciprofloxacin HCl/dexamethasone provides a treatment option with low potential for ototoxicity in patients with tympanostomy tubes or known perforation of the tympanic membrane.

### **Common Drug Review**

**Summary of Committee Considerations:**

The Committee considered a systematic review of three randomized controlled trials (RCTs) of ciprofloxacin HCl/dexamethasone in patients with acute otitis media and one RCT in patients with acute otitis externa.

Ciprofloxacin HCl/dexamethasone (Ciprodex<sup>®</sup>) costs \$25.20 for a 7.5 mL bottle which is more expensive than other topical otic antibiotic/corticosteroid combination products: framycetin/gramicidin/dexamethasone cost \$7.84 for 8 mL, polymixin/neomycin/hydrocortisone costs \$10.14 for 10 mL and gentamicin/betamethasone costs \$8.97 for 7.5 mL.

**Of Note:**

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.
2. The Committee considered data on the ototoxicity of various agents in patients with otitis media with perforation of the tympanic membrane or tympanostomy tubes. While the Committee recognizes the place in therapy of ciprofloxacin HCl/dexamethasone in selected patients with non-intact tympanic membranes other, less costly management options are available for the treatment of acute otitis media and otitis externa.