



CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

CIPROFLOXACIN HCL and DEXAMETHASONE OTIC SUSPENSION (Ciprodex® – Alcon Canada Inc.)

Ciprodex® 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.

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that ciprofloxacin HCl/dexamethasone otic suspension not be listed.

Reasons for the recommendation:

1. For patients with otitis externa, one randomized trial of relatively poor quality (allocation concealment unclear) compared topical otic ciprofloxacin HCl/dexamethasone with neomycin, polymixin B and hydrocortisone (NPH) 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. The clinical importance of these differences is not obvious. The results of this study did not justify the increased cost of topical ciprofloxacin HCl/dexamethasone.
2. For patients with otitis media with tympanostomy tubes, available studies compare ciprofloxacin HCl/dexamethasone otic suspension with ciprofloxacin ophthalmic solution and with ofloxacin otic solution. In both trials, topical ciprofloxacin HCl/dexamethasone resulted in a slightly greater improvement in symptoms, but the clinical significance of the differences was not obvious. Because of the availability of less costly alternatives that are not ototoxic, the Committee recommends that topical ciprofloxacin HCl/dexamethasone not be funded.

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.
2. The Committee considered the data on ototoxicity of various agents in patients with otitis media plus perforation or tympanostomy tubes. Other, less costly options that have similar evidence of harm compared to ciprofloxacin HCl/dexamethasone are available.