

Anti-Infective Drugs Advisory Committee
November 7, 2001

Questions for the Advisory Committee (11/2/01)

Product-Specific Questions

1. Do the data support the safety and efficacy of a single dose (30 mg/kg) and/or of the three-day regimen (10 mg/kg/day for 3 days) of azithromycin for the treatment of AOM?

In your discussion, please comment on the significance of the following and how they contributed to your recommendation: interpretation of the data from clinical-only studies, studies with tympanocentesis at baseline (single-tap), the natural history of the infection, and information from the published literature.

- a) If yes, should any caveats be included in the label based on the results of the studies with tympanocentesis at baseline (single-tap)?
 - b) If no, what additional study (-ies) do you recommend?
2. If approval of the single-dose regimen is recommended, what advice should be given to prescribers and patients regarding the increased vomiting associated with the use of this regimen?

Clinical Trials Issues

3. Current guidance for AOM trial designs suggests one clinical-only study and one single-tap study (which may be non-comparative). Please discuss the following issues
 - a) Should clinical-only trials continue, or should all enrolled patients have a tympanocentesis at baseline?
 - b) Should non-comparative microbiology studies continue?
 - c) Should guidance incorporate stratification by age (< 2 years)? If so, what proportion of patients should be under the age of 2 years?

In your discussion, please comment on the merits of studies with clinical information only, studies with tympanocentesis, ideal timing of clinical assessments (end-of-therapy v. later follow-up), and alternative study designs (comparative trials with microbiology, double-tap studies, placebo-controlled studies with early escape).