

June 2, 2004,
Arthritis Advisory Committee Meeting Briefing Package
Errata Sheet to Tab #2: "Oxypurinol Summary"

1. Page 2, Table 1.
Age range for study AAI-US-175 is 27-80 (mean: 58.9)
2. Page 5, Analyses of gout attacks:
The correct numbers are: Twelve patients (15.2%) had gout flares.
 - Five had flares during OXPL213
 - Four had flares during OXPL213-A4
 - Three had flares during both the base and extension phase.
3. Page 11, first paragraph after bullets:
This paragraph should read:
Therefore, 18 of 26 patients (69%) who had failed documented allopurinol re-challenge or desensitization were able to tolerate oxypurinol without further allergic reactions for up to 14 weeks.
Additional information is pending at the time of this review.
4. Page 11, AAI-US-175, third bullet: Relative bioavailability of oxypurinol is about 30% of that from allopurinol based on acute, not chronic, dosing data. The paragraph should read:

Relative bioavailability of oxypurinol single dose is about 30 % of that from allopurinol. Based on oxypurinol exposure, equivalent allopurinol doses from oxypurinol single doses of 100, 300, 600 and 800 mg are approximately 58, 78, 81 and 112 mg, respectively.