

Follow-Up Adverse Event Review: Esmolol

**Pediatric Advisory Committee Meeting
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Background Drug Information

- **Drug:** Brevibloc[®] (esmolol HCL) Tablets
- **Therapeutic Category:** Beta blocker
- **Sponsor:** Baxter Healthcare Corporation
- **Indication (adult):** Treatment of SVT; intra- and post-operative tachycardia and/or hypertension
- **No Pediatric Indication**
- **Original Market Approval:** December 31, 1986
- **Pediatric Exclusivity Granted:** August 22, 2003
- **Previous PAC AE Review:** February 14, 2005

Pediatric Adverse Events Since Market Approval (n=13*)

Presented to PAC February 2005

- Pediatric reports*:
 - 13 reports (13 US)
 - 9 serious (9 US)
 - 3 deaths (3 US)

*Counts may include duplicate reports

Follow-up Adverse Event Review

There were no new reports of pediatric adverse events since the 2005 PAC presentation.

Summary: Esmolol

- There were no new reports of pediatric adverse events since the last PAC presentation.
- Pediatric use is limited (~ 1% of all prescriptions)¹.
- This completes the follow-up report to the 1-year AE review.
- FDA recommends routine monitoring of AEs for esmolol in all populations.

Does the Advisory Committee concur?

¹ Premier Healthcare Informatics, RxMarket Advisor™ data extracted October 2007

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