

One Year Post Exclusivity Adverse Event Review: Sumatriptan

**Pediatric Advisory Committee Meeting
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Background Drug Information

- **Drug:** Imitrex[®] (sumatriptan) nasal spray
- **Therapeutic Category:** Selective 5-hydroxytryptamine receptor agonist
- **Sponsor:** GlaxoSmithKline
- **Indication:** Acute treatment of migraine attacks with or without aura in adults. Not recommended for use in patients under 18 years of age.
- **Original Market Approval:** August 26, 1997
- **Pediatric Exclusivity Granted:** February 18, 2004

Sumatriptan Nasal Spray

- Pediatric Information Added to the Label:
 - Two controlled clinical trials (12-17 year old patients, N=1248)
 - Adverse events were similar to those reported for adults
 - Studies did not establish efficacy compared to placebo
- Pediatric patients accounted for less than 5% (3,104-3,468 prescriptions) of all paid prescription claims for Imitrex[®] nasal spray from 3/02 to 2/05.¹
- Six unduplicated pediatric adverse event reports identified during the one-year post-exclusivity period:
 - None of the reports were serious or life-threatening

¹Caremark Dimension Rx™, Mar 2002 - Feb 2005, Data extracted Mar 23, 2005

Summary:

Sumatriptan Nasal Spray

- No new concerning unlabeled safety signals identified in pediatric adverse events reported through AERS in the one-year post-exclusivity period.
- This completes the one-year post-exclusivity AE reporting as mandated by BPCA.
- FDA recommends routine monitoring of AEs for sumatriptan in all populations.
- Does the Advisory Committee concur?

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