

One Year Post Exclusivity Adverse Event Review: Anagrelide

**Pediatric Advisory Committee Meeting
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Background Drug Information

- **Drug:** Agrylin[®] (anagrelide)
- **Therapeutic Category:** Platelet-reducing agent
- **Sponsor:** Shire
- **Indication:** Treatment of patients with thrombocythemia, secondary to myeloproliferative disorders
 - Reduce platelet count and thrombosis risk
 - Ameliorate symptoms (e.g. thrombo-hemorrhagic events)
- **Original Market Approval:** March 14, 1997
- **Pediatric Exclusivity Granted:** May 25, 2004

Summary: Anagrelide

- Exclusivity studies resulted in labeling describing pharmacokinetics and clinical study results
- Pediatric use limited (0.2 – 0.3% of all prescriptions)¹
- In the one-year post-exclusivity period, no pediatric AEs reported
- This completes the one-year post-exclusivity AE reporting as mandated by BPCA.
- FDA recommends routine monitoring of AEs for anagrelide in all populations.
- Does the Advisory Committee concur?

¹Verispan LLC, Jun 2002 – May 2005, Data extracted Sep 2005

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