

One Year Post Exclusivity Adverse Event Review: Irinotecan

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Background Drug Information

- **Drug:** Camptosar[®] (irinotecan hydrochloride) injection
- **Therapeutic Category:** Antineoplastic agent
- **Sponsor:** Pfizer
- **Indication:** A component of first-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum. Effectiveness in pediatric patients has not been established.
- **Original Market Approval:** June 14, 1996
- **Pediatric Exclusivity Granted:** March 10, 2004
- **Pediatric Information Added to the Label:** PK (clearance and AUC) and adverse event data from the exclusivity studies were added to the label:
 - Pediatric adverse events in the exclusivity trials were neutropenia, diarrhea, dehydration, hypokalemia, hyponatremia, and infection.
 - Accrual to the single agent irinotecan phase was halted due to high rate of progressive disease (28.6%) and the early deaths (14%).

Irinotecan Hydrochloride

- Use information difficult to obtain since the data resources available to the agency do not capture the use of irinotecan in the outpatient clinic setting, which represents approximately 75% of use.
- PremierTM database revealed pediatric use in 16% (205 discharges) of discharges in which irinotecan was billed between 10/02 and 9/04.¹
- 9 (4 unduplicated) pediatric AE reports during one-year post-exclusivity period:
 - 2 deaths
 - Wilms' tumor progression
 - Paraneoplastic meningoencephalitis associated with neuroblastoma

¹ Premier Rx Market Advisor, Oct 2002 – Sept 2004, Data extracted April 2005.

Summary: Irinotecan Hydrochloride

- No new unexpected 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 irinotecan in all populations.
- Does the Advisory Committee concur?

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