

Clinical Evaluation Report (CER)

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Product: 00002-3227 (Source: FAERS)

Total Events: 100, Serious Events: 76

Top Reported Events:

- Haematuria: 4
- Drug hypersensitivity: 4
- Convulsion: 3
- Deep vein thrombosis: 3
- Ovarian germ cell cancer stage II: 2

Clinical Evaluation Narrative

Clinical Evaluation Report (CER)

Product Code: 00002-3227

Executive Summary This Clinical Evaluation Report (CER) provides a comprehensive analysis of the post-market safety data for the product identified by the code 00002-3227. The data, sourced from the FDA Adverse Event Reporting System (FAERS), includes a total of 100 reported events, with 76 classified as serious. The analysis period spans from March 2014 to December 2017, with a forecast extending into January 2018. Key adverse events reported include haematuria, drug hypersensitivity, convulsion, deep vein thrombosis, and ovarian germ cell cancer stage II. This report aims to assess the trends, forecast potential future events, analyze anomalies, and evaluate the overall benefit-risk profile of the product.

Description of Trends The data indicates a significant spike in reports at the beginning of the tracking period in March 2014, with 68 reports, followed by a sharp decline in subsequent months. From April 2014 onwards, the monthly report count stabilized to lower single digits, with several months reporting zero events. This trend suggests an initial surge in reporting possibly due to heightened awareness or reporting incentives, which normalized over time.

Forecast Interpretation The forecast for January 2018 suggests a slight increase in reports to approximately 1.81 events. This forecast is based on historical data and indicates a low level of reporting consistent with the trend observed in the latter part of the analysis period. The forecasted value, while not indicative of a significant risk increase, warrants continued surveillance.

Analysis of Anomalies Anomalies in the data were detected on specific dates where the reported events were significantly different from expected patterns. These anomalies occurred on: - 2014-09-30: 3 events - 2015-01-31: 1 event - 2015-02-28: 3 events - 2015-09-30: 1 event - 2016-02-29: 1 event - 2017-05-31: 1 event - 2017-12-31: 1 event

These anomalies may be attributed to external factors such as changes in reporting practices, increased usage, or heightened awareness due to media or scientific publications. Each anomaly was isolated and did not establish a new trend.

Benefit-Risk Considerations The benefit-risk profile of the product is evaluated by considering the severity and frequency of reported adverse events against the therapeutic benefits of the product. The most frequently reported serious events include conditions that range from moderate (haematuria, drug hypersensitivity) to severe (ovarian germ cell cancer stage II). The occurrence of serious events in 76% of reports is significant and necessitates ongoing monitoring and investigation.

However, the overall frequency of reports has shown a decreasing trend, and the forecast suggests a continuation of low-level event reporting. This may indicate that initial concerns may have been addressed or that the product's risk factors are well-managed through current clinical use guidelines.

Conclusion Based on the analysis of the FAERS data, the product identified by code 00002-3227 demonstrates a manageable safety profile with a decreasing trend in reported adverse events. The forecast suggests continued low-level reporting, and anomalies do not indicate a worsening safety trend. Ongoing surveillance and periodic re-evaluation of the benefit-risk balance are recommended to ensure continued patient safety and product efficacy.