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 Product Code 00002-3227, as reported in the FDA Adverse Event Reporting System (FAERS). The analysis covers a period from March 2014 to December 2017, with a total of 100 reported events. Of these, 76 were classified as serious. The top reported events include Haematuria and Drug hypersensitivity (each with 4 reports), followed by Convulsion, Deep vein thrombosis (each with 3 reports), and Ovarian germ cell cancer stage II (2 reports). This report aims to assess the trends, forecast potential future events, analyze anomalies, and evaluate the benefit-risk balance of the product.

Description of Trends The data indicates a significant spike in reports at the beginning of the observation period, with 68 reports in March 2014, which sharply declined to 7 by April 2014 and stabilized to lower levels thereafter. From August 2014 onwards, the monthly reports were generally low, with several months reporting zero events. This suggests an initial surge in reporting possibly due to heightened awareness or a batch-specific issue, followed by a normalization of reporting frequency.

Forecast Interpretation The forecast for January 2018 suggests an expected count of approximately 1.81 events. This forecast is based on historical data and indicates a low level of expected adverse event reports moving forward, assuming no changes in product usage or patient population.

Analysis of Anomalies Several anomalies were detected throughout the reporting period, specifically on dates where the reported events were significantly different from expected trends. These include: - September 2014: 3 reports - January 2015: 1 report - February 2015: 3 reports - September 2015: 1 report - February 2016: 1 report - May 2017: 1 report - December 2017: 1 report

These anomalies could be related to external factors such as increased product usage, reporting campaigns, or changes in reporting regulations. Each anomaly was isolated and did not indicate a recurring pattern that would suggest ongoing product safety issues.

Benefit-Risk Considerations The benefit-risk profile of Product Code 00002-3227 must consider the severity and frequency of reported adverse events against the therapeutic benefits of the drug. While the initial surge in reports was concerning, the rapid decline and low level of ongoing reports suggest that the initial issues were adequately addressed or were not indicative of systemic product safety issues. The serious nature of some reported events, such as Ovarian germ cell cancer stage II, requires ongoing surveillance to ensure these risks are appropriately communicated to healthcare providers and patients.

Conclusion Based on the analysis of the FAERS data, Product Code 00002-3227 demonstrates a manageable safety profile with a low frequency of serious adverse events post-initial reporting period. The forecast suggests continued low levels of adverse event reports. Ongoing monitoring and analysis of incoming data will be crucial to promptly identify any changes in the safety profile of the drug. The benefit-risk balance remains favorable, with the benefits of the drug outweighing the risks when used as directed in the appropriate patient population.

This report supports the continued approval and monitoring of Product Code 00002-3227, with recommendations for periodic re-evaluation of the safety data to ensure patient safety and product efficacy.