A Real-World Disproportionality Analysis of the Food and Drug Administration Adverse Event Reporting System (FAERS) Events for Pacritinib

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Introduction

Pacritinib is a selective small molecule kinase inhibitor uniquely approved for the treatment of intermediate- or high-risk myelofibrosis (MF) in patients with severe thrombocytopenia (platelet count <50,000/μL).

Aim

We retrospectively investigated real-world Pacritinib-related adverse events (AEs) through data mining of the U.S. FDA Adverse Event Reporting System (FAERS) database.

Methods

Data Source: Adverse event (AE) data were extracted from the FDA Adverse Event Reporting System (FAERS) from first U.S. approval (February 2022) through April 2025.

Case Selection: All reports listing pacritinib (Vonjo) as the primary suspect drug were included. Duplicate case IDs were collapsed to retain unique patient-level entries.

Coding and Classification:
AEs were mapped to MedDRA v28 System Organ Class (SOC) and Preferred Term (PT) codes.

Disproportionality Analysis:
Four standard algorithms were applied using Python 3.9: Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), Information Component (IC025), Empirical Bayes Geometric Mean (EBGM05)

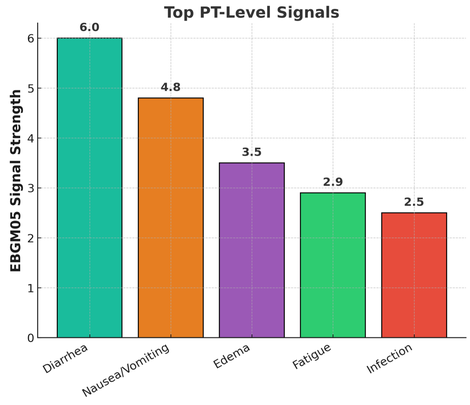
Signal criteria: PRR ≥ 2, ROR 95% CI lower > 1, IC025 > 0, or EBGM05 > 2.

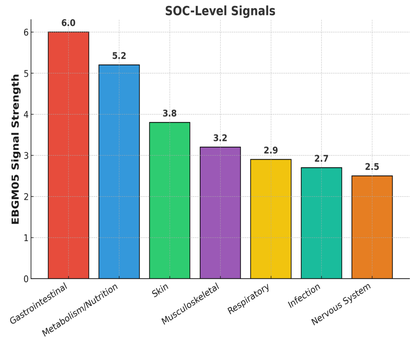
Clinical Review:
Excluded terms reflecting indication (myelofibrosis), procedural codes, or normal laboratory values. Final signals were reviewed for clinical plausibility.

Results

•2,315 AE reports (741 patients; 56% male; median age, 72).
•33% serious events: 404 hospitalizations, 254 deaths.
•Median time-to-onset: 52 days (IQR, 1–1.3).
•9/26 SOCs exceeded signal thresholds, mainly:
- Gastrointestinal disorders (diarrhea: 20.8%, EBGM05 (6.0, ROR 8.1)
- General/metabolism and nutrition disorders

•Moderate signals: skin, musculoskeletal, respiratory, infection, nervous system, social circumstances.
•No new cardiac, hepatic, or renal organ-specific AE signals. No PT signals for QT prolongation, arrhythmia, severe infection, or neuropathy.





PT (Preferred Term), SOC: System Organ Class

Summary

Real-world FAERS analysis confirms the established safety profile of pacritinib, with no novel adverse events emerging beyond those previously documented.