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Post-Marketing Safety Profile of Suzetrigine:

A Pharmacovigilance Analysis of the FDA Adverse Event Reporting System (FAERS)

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BACKGROUND

- Suzetrigine is a first-in-class selective Nav1.8 inhibitor approved for the treatment of moderate-to-severe acute pain.
- While clinical trials demonstrated a favorable safety profile, real-world post-marketing safety data remain limited.
- The FDA Adverse Event Reporting System (FAERS) provides an opportunity to evaluate adverse events reported in routine clinical use.

OBJECTIVE

- To characterize the adverse event profile of suzetrigine using post-marketing reports submitted to FAERS.

METHODS

- Data source: FAERS (January 2025 – June 2026)
- Reports listing suzetrigine as the suspected drug
- Descriptive analysis of demographics, reporter type, seriousness, and adverse events (MedDRA SOC and PT)
- Domestic vs, foreign reports
- Frequencies and percentages calculated using total reports (N = 1,338)

LIMITATIONS

- Spontaneous reporting system
- Underreporting and reporting bias
- Cannot determine causality or incidence

REAL-WORLD DATA. REAL PATIENT EXPERIENCES.

1,338 FAERS reports involving suzetrigine

89.2% of reports were **non-serious.**

What are patients reporting after starting suzetrigine?

Itching and rash lead the early FAERS reports, with **neurologic symptoms** also prominent.

Pruritus **11.8%** (158 reports)

Rash **9.7%** (130 reports)

Paraesthesia **6.7%** (90 reports)

Dizziness **5.8%** (78 reports)

INFORMING SAFER USE. IMPROVING PATIENT CARE.

Top 5 System Organ Classes (SOCs)

Nervous system disorders	406 (30.3%)
Skin and subcutaneous tissue disorders	387 (28.9%)
General disorders and administration site conditions	270 (20.2%)
Injury, poisoning and procedural complications	269 (20.1%)
Gastrointestinal disorders	243 (18.2%)

Top 5 Clinical Preferred Terms (PTs)

Pruritus	158 (11.8%)
Rash	130 (9.7%)
Paraesthesia	90 (6.7%)
Nausea	83 (6.2%)
Dizziness	78 (5.8%)

Reporter Type

- Consumer 704 (52.6%)
- Healthcare professional 625 (46.7%)
- Other/Unknown 9 (0.7%)

Serious Outcomes

Non-serious	1,194 (89.2%)
Hospitalization	57 (4.3%)
Other serious event	88 (6.6%)
Required intervention	11 (0.8%)
Life-threatening	9 (0.7%)
Disability	8 (0.6%)
Death	7 (0.5%)

Scan to view the full abstract, complete results, and references.

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