FAERS Signal Dossier

FAERS SIGNAL DOSSIER - FREE SAMPLE REPORT

One drug. One finished safety report.

Report ID: FSD-SAMPLE-20261029 - Semaglutide, primary-suspect analysis

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Semaglutide

Real-world adverse-event signals from FDA FAERS, computed and explained. One drug, one finished report - benchmarked against Exenatide.

Read this first. FAERS is a spontaneous reporting system. These numbers describe *reports*, not patients, and a reporting signal is **not** proof that a drug caused an event. FAERS has no exposure denominator, so no incidence rate can be calculated from it. Reports may be duplicated, incomplete, or stimulated by media coverage. This dossier is a research snapshot, not medical advice. **Not affiliated with, endorsed by, or sponsored by the U.S. Food and Drug Administration. FAERS data are public FDA data, analyzed independently.**

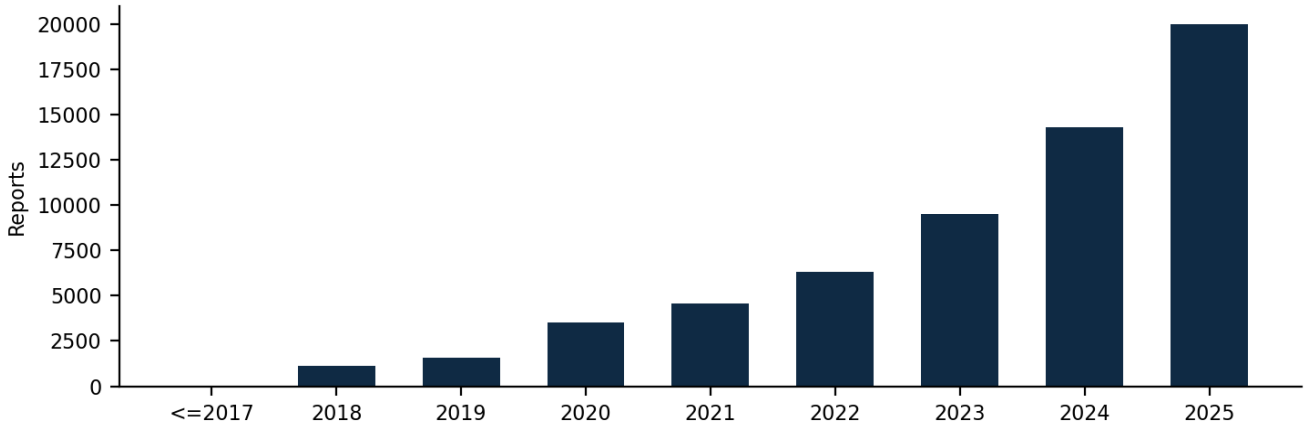
72,856	49.5%	52,311	30 Jun 2026
REPORTS - SEMAGLUTIDE AS PRIMARY SUSPECT	OF REPORTS FLAGGED SERIOUS	COMPARATOR - EXENATIDE	LATEST REPORT IN THIS SNAPSHOT

Source: OpenFDA drug/event (FDA FAERS public data) — reports where Semaglutide is coded primary suspect (drugcharacterization = 1), retrieved 2026-10-29. Snapshot total: 20,692,690 reports.

Bottom line

- The semaglutide reporting profile is led by Nausea, Vomiting, Diarrhea - the most frequently coded clinical events in this snapshot.
- Impaired Gastric Emptying has the largest disproportionality estimate in the top-event set (ROR 117.2; 95% CI 112.7-121.9). That is a reporting signal for closer study, not evidence of causation.
- 10 of the top-10 events meet the classic signal criteria (PRR at least 2, chi-square at least 4, at least 3 cases).
- 49.5% of semaglutide reports carry a serious flag, versus 28.0% for the comparator. Read the gap as a difference in reporting mix and product history, not a head-to-head safety verdict.

1 - Reporting trend

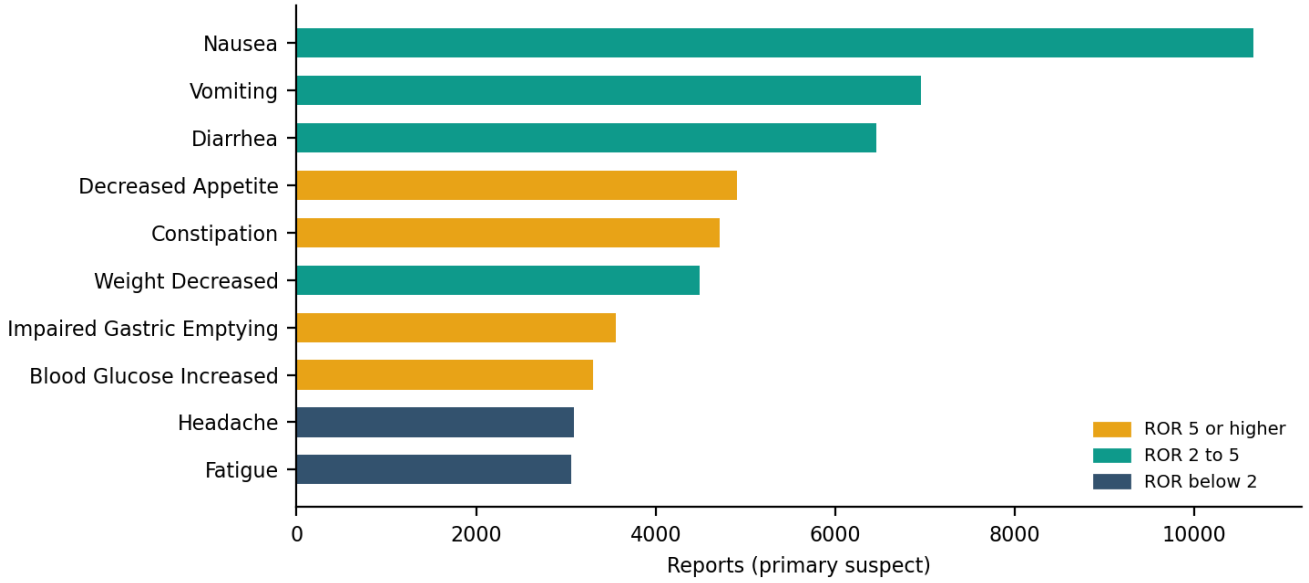


Period	Reports
<=2017	40

Period	Reports
2018	1,142
2019	1,595
2020	3,515
2021	4,559
2022	6,302
2023	9,483
2024	14,287
2025	19,977

Source: OpenFDA drug/event — count of Semaglutide primary-suspect reports by receivedate year, retrieved 2026-10-29. A rising count tracks expanding use and attention; on its own it says nothing about rising risk. The most recent year may be partial.

2 - Most common adverse events



Bar color codes the Reporting Odds Ratio (ROR) for each event from Section 3: amber = ROR 5 or higher, teal = ROR 2 to 5, slate = ROR below 2.

Recent reporting by quarter

Quarter	Reports
2023 Q4	1,556
2024 Q1	3,954
2024 Q2	2,015
2024 Q3	5,848
2024 Q4	2,470
2025 Q1	2,842
2025 Q2	2,690
2025 Q3	11,804
2025 Q4	2,641
2026 Q1	2,604

Quarter	Reports
2026 Q2	9,352
2026 Q3	0

Source: OpenFDA drug/event - count of Semaglutide primary-suspect reports by receivedate quarter for the last 12 quarters, retrieved 2026-10-29. The current quarter may be partial.

Preferred Term	Reports	Share
Nausea	10,663	14.6%
Off Label Use	7,316	10.0%
Vomiting	6,958	9.6%
Diarrhea	6,454	8.9%
Decreased Appetite	4,901	6.7%
Constipation	4,718	6.5%
Weight Decreased	4,486	6.2%
Impaired Gastric Emptying	3,558	4.9%
Product Use In Unapproved Indication	3,475	4.8%
Blood Glucose Increased	3,302	4.5%
Headache	3,093	4.2%
Fatigue	3,058	4.2%
Abdominal Pain Upper	3,037	4.2%
Wrong Technique In Product Usage Process	3,015	4.1%
Weight Increased	2,609	3.6%

Source: OpenFDA drug/event — count of MedDRA Preferred Terms (patient.reaction.reactionmeddrapt) across Semaglutide primary-suspect reports, retrieved 2026-10-29. Administrative terms (for example "Off label use") are counted for completeness, are not clinical events, and are excluded from the chart and from signal interpretation. A report can carry more than one term, so shares do not sum to 100%.

3 - Disproportionality: does a signal stand out?

The Reporting Odds Ratio (ROR) and Proportional Reporting Ratio (PRR) compare reporting for this drug with all other reports in FAERS. A value near 1 means similar relative reporting. The flag marks the classic Evans signal criteria: PRR at least 2, chi-square at least 4, and at least 3 cases. Meeting the criteria identifies a signal worth investigating; it never proves the drug caused the event.

Preferred Term	Reports	ROR (95% CI)	PRR (95% CI)	Chi-sq	Signal
Nausea	10,663	4.4 (4.3-4.5)	3.9 (3.9-4.0)	23,873	YES
Off Label Use	7,316	2.6 (2.5-2.7)	2.4 (2.4-2.5)	6,422	YES
Vomiting	6,958	4.7 (4.6-4.8)	4.3 (4.2-4.4)	17,895	YES
Diarrhea	6,454	3.1 (3.0-3.2)	2.9 (2.8-3.0)	8,247	YES
Decreased Appetite	4,901	6.6 (6.4-6.8)	6.2 (6.0-6.4)	21,158	YES
Constipation	4,718	6.8 (6.6-7.0)	6.4 (6.2-6.6)	21,213	YES
Weight Decreased	4,486	4.9 (4.8-5.1)	4.7 (4.6-4.8)	12,973	YES
Impaired Gastric Emptying	3,558	117.2 (112.7-121.9)	111.5 (107.4-115.9)	279,737	YES

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Preferred Term	Reports	ROR (95% CI)	PRR (95% CI)	Chi-sq	Signal
Product Use In Unapproved Indication	3,475	4.3 (4.2-4.4)	4.1 (4.0-4.3)	8,251	YES
Blood Glucose Increased	3,302	5.3 (5.1-5.5)	5.1 (4.9-5.3)	10,778	YES

Source: calculated by the author from OpenFDA drug/event counts — 2x2 tables of Semaglutide primary-suspect reports vs all other reports in the same snapshot (20,692,690 reports), retrieved 2026-10-29.

Signal persistence: the strongest signal above, Impaired Gastric Emptying, has an all-time ROR of 117.2. Recomputed on 2023-2026 reports only (55,703 Semaglutide reports), its ROR is 96.9 (95% CI 92.3-101.8) - so the signal remains visible in recent reporting.

Source: calculated by the author from OpenFDA drug/event counts restricted to receivedate 2023-2026, retrieved 2026-10-29.

4 - Serious outcomes

Outcome flag	Reports	Share
Death	1,267	1.7%
Life-threatening	1,326	1.8%
Hospitalization	14,279	19.6%
Disability	1,539	2.1%
Other serious	26,854	36.9%
Serious (any)	36,040	49.5%

Source: OpenFDA drug/event — seriousness flags (serious, seriousnessdeath, seriousnesshospitalization, and related fields) on Semaglutide primary-suspect reports, retrieved 2026-10-29. Comparator serious share: 28.0% of 52,311 reports; death share: 3.4%.

5 - Who reports, and who is affected

Reporter type	Share
Consumer / non-health professional	70.2%
Physician	15.0%
Other health professional	9.5%
Pharmacist	3.7%
Lawyer	1.3%

Patient sex	Share
Female	58.0%
Male	32.4%
Not specified	0.0%

Age group	Share
Adult	16.2%
Elderly	5.8%
Adolescent	0.0%
Neonate	0.0%
Child	0.0%
Infant	0.0%

Top reporter countries	Share

Source: OpenFDA drug/event — primarysource.qualification, patient.patientsex, patient.patientagegroup, and primarysource.reportercountry counted across Semaglutide primary-suspect reports, retrieved 2026-10-29. Shares use all 72,856 reports as the denominator, including reports where the field is blank, so rows may sum to less than 100%.

Top events by patient sex

Women - event	Reports	Men - event	Reports
Nausea	7,122	Nausea	2,763
Off Label Use	4,851	Diarrhea	2,202
Vomiting	4,466	Vomiting	1,937
Diarrhea	3,800	Off Label Use	1,920
Constipation	3,026	Decreased Appetite	1,709
Decreased Appetite	2,957	Weight Decreased	1,657

Source: OpenFDA drug/event - MedDRA Preferred Term counts (patient.reaction.reactionmeddrapt) within Semaglutide primary-suspect reports, split by patient.patientsex (2 = female, 1 = male); reports with unspecified sex are excluded here, retrieved 2026-10-29.

Sampled medians by sex: median age at onset 64 years in women (n=495) vs 67 in men (n=282); median weight 86 kg in women (n=129) vs 97 kg in men (n=75) (from the section 9 record-level sample).

Reports by brand name (top 5)

Brand name	Reports
Ozempic	65,913
Metformin	7,627
Rybelsus	7,338
Medline	4,207
Jardiance	3,468

Source: OpenFDA drug/event - patient.drug.openfda.brand_name counted across Semaglutide primary-suspect reports, retrieved 2026-10-29.

Report types as recorded: Type 1 (68,157 reports); Type 2 (4,418 reports); Type 3 (278 reports); Type 4 (2 reports). Source: OpenFDA drug/event - reporttype field counted across Semaglutide primary-suspect reports, retrieved 2026-10-29.

6 - Outcome matrix: the ten most common clinical events

For each of the ten most common clinical events: how often the reports carrying that event were flagged with each serious outcome. A report can carry several flags.

Preferred Term	Reports	Death	Hospitalization	Disability	Life-threatening
Nausea	10,663	0.8%	24.3%	1.7%	1.7%
Vomiting	6,958	1.2%	36.7%	1.9%	2.5%
Diarrhea	6,454	1.0%	29.0%	1.6%	1.9%
Decreased Appetite	4,901	1.0%	23.1%	1.0%	1.5%
Constipation	4,718	0.6%	28.0%	1.4%	1.1%
Weight Decreased	4,486	1.0%	14.8%	1.6%	1.3%
Impaired Gastric Emptying	3,558	0.9%	57.4%	1.2%	2.8%
Blood Glucose Increased	3,302	0.6%	13.3%	1.1%	1.2%
Headache	3,093	0.5%	13.8%	2.0%	1.0%
Fatigue	3,058	0.7%	16.5%	3.1%	1.5%

Source: OpenFDA drug/event - for each event, the share of Semaglutide primary-suspect reports carrying that MedDRA term that are also flagged seriousnessdeath, seriousnesshospitalization, seriousnessdisabling, or seriousnesslifethreatening = 1, retrieved 2026-10-29. These are reporting proportions, not fatality or hospitalization rates.

7 - Report context: other drugs and indications in the same reports

Other drug in the same reports	Reports
Oral Semaglutide	72,856
Metformin	7,627
Metformin Er 500 Mg	7,627
Metformin Er 750 Mg	7,627
Insulin Glargine	3,877
Empagliflozin	3,468
Aspirin	3,324
Aspirin 325 Mg	3,247
Aspirin 81 Mg	3,247
Gabapentin	2,845

Source: OpenFDA drug/event — patient.drug.openfda.generic_name counted across Semaglutide primary-suspect reports (the target drug itself excluded), retrieved 2026-10-29. Co-reported drugs are context for confounding, not suspects.

Indication recorded in these reports	Reports
Product Used For Unknown Indication	28,239
Type 2 Diabetes Mellitus	21,719
Diabetes Mellitus	5,741
Weight Control	5,566
Product Used For Unknown Indication	4,970
Type 2 Diabetes Mellitus	3,285
Hypertension	2,318
Glucose Tolerance Impaired	1,754
Obesity	1,612
Blood Cholesterol Increased	1,438

Source: OpenFDA drug/event — patient.drug.drugindication counted across the same reports (all drug entries), retrieved 2026-10-29.

Top events within the leading indication (Product Used For Unknown Indication)

Preferred Term	Reports
Nausea	3,528
Vomiting	2,435
Diarrhea	2,219
Weight Decreased	1,746
Off Label Use	1,718
Decreased Appetite	1,503

Source: OpenFDA drug/event - MedDRA Preferred Term counts within Semaglutide primary-suspect reports whose recorded indication is Product Used For Unknown Indication, retrieved 2026-10-29.

8 - Comparator snapshot

How the comparators were chosen: Comparators selected automatically: same FDA-established pharmacologic class (GLP-1 Receptor Agonist [EPC]), oldest FDA approvals first: EXENATIDE (approved 2005); LIRAGLUTIDE

(approved 2010) Comparators are older drugs in the same FDA-established pharmacologic class — the same mechanism family — so the benchmark is a fair one. Shown for context only; different reporting histories make direct safety comparisons invalid.

Comparator 1 — Exenatide (52,311 primary-suspect reports; serious share 28.0%; death share 3.4%)

Comparator Preferred Term	Reports	Share
Blood Glucose Increased	15,472	29.6%
Weight Decreased	12,124	23.2%
Nausea	12,040	23.0%
Decreased Appetite	5,643	10.8%
Blood Glucose Decreased	5,516	10.5%

Source: OpenFDA drug/event - Exenatide primary-suspect reports, MedDRA Preferred Term counts, retrieved 2026-10-29.

Comparator 2 — Liraglutide (50,605 primary-suspect reports; serious share 48.6%; death share 3.7%)

Comparator Preferred Term	Reports	Share
Nausea	7,290	14.4%
Blood Glucose Increased	4,091	8.1%
Vomiting	3,598	7.1%
Diarrhea	3,455	6.8%
Pancreatitis	2,355	4.7%

Source: OpenFDA drug/event - Liraglutide primary-suspect reports, MedDRA Preferred Term counts, retrieved 2026-10-29.

9 - Dose, dosage form, route, and treatment duration (record-level sample of 2,000 recent reports)

The OpenFDA count API cannot aggregate free-text dose fields, so this section is computed at record level: the 2,000 most recent Semaglutide primary-suspect reports were read in full and their drug entries analyzed directly. Figures here describe that sample, not the full 72,856 reports.

Dosage forms recorded for the suspect drug

Dosage form	Records
Solution For Injection	276
Injection	51
Tablet	32
Solution For Injection In Pre-Filled Pen	8
Solution For Injection/Skin-Prick Test	3
Solution For Injection In Pre-Filled Syringe	2
Suspension For Injection	2
Unknown	1
Tablet (Unspecified)	1
Solution For Infusion	1

Routes of administration recorded for the suspect drug

Route code (as recorded)	Records
Code 058	138

Route code (as recorded)	Records
Code 065	21
Code 048	2
Code 061	1
Code 030	1

Route completeness: a route code was recorded on 163 of the sampled suspect-drug entries; a dosage form on 379. FAERS route codes are numeric and their meaning is not consistent across reporting eras and submitting systems, so codes are shown exactly as recorded rather than relabeled - the dosage-form table above is the reliable guide to how the drug was given (tablet vs injection vs infusion).

Dose text exactly as recorded (most frequent)

Recorded dose	Records
UNK UNK, UNKNOWN	38
UNK, UNKNOWN	9
1 MG	6
NOT REPORTED	6
0.25 MG QW	6
0.25 MG	5
0.5 MG	5
1 MILLIGRAM, WEEKLY (0.25 OR 0.5 MG/DOSE, 2 MG/3M, INTO THE	5
1 DOSAGE FORM, QD (IN PRE-FILLED PEN)	4
DOSE DECREASED	4

Treatment duration (therapy start and end dates both recorded, n=136): median 42 days; middle half 8 to 154 days.
Patient age at onset in the sample: median 64 years (middle half 55 to 72; n=1,207).
Patient weight in the sample: median 87 kg (n=318).

Source: OpenFDA drug/event - full records of the 2,000 most recent Semaglutide primary-suspect reports; suspect-drug entries (drugcharacterization = 1 matching this drug): drugdosageform, drugadministrationroute (numeric codes, shown as recorded), drugdosagetext (verbatim, not normalized - the same dose can appear in several formats), drugstartdate and drugenddate, patientonsetage with patientonsetageunit, patientweight (kg), retrieved 2026-10-29.

Parsed daily-dose bands: where the recorded dose text followed a strict amount + unit + frequency pattern, the most common daily doses were: 0.25 mg/day (9 records); 0.5 mg/day (9 records); 1 mg/day (6 records); 7 mg/day (4 records); 3 mg/day (2 records). Parsed unambiguously for 32 of 812 dose records in the sample; the rest were free-form and are shown verbatim above rather than guessed.

Sole-suspect share: in 1,002 of the 2,000 sampled reports (50%), Semaglutide was the only drug coded as a suspect - the cleanest reports for signal reading; the rest list co-suspects that may confound.

Action taken with the drug after the event (sampled)

Action taken	Records
Unknown	1,352
Drug withdrawn	590
Dose not changed	208
Not applicable	83
Dose reduced	68
Dose increased	38

Source: OpenFDA drug/event - patient.drug.actiondrug on suspect-drug entries in the section 9 sample; recorded on 2,339 entries, retrieved 2026-10-29.

Rechallenge (sampled): Unknown: 400; Positive rechallenge (event recurred): 10; Negative rechallenge (no recurrence): 5. Recorded on only 415 sampled suspect-drug entries, so read this as a small, selected subset - most reports never test re-administration. Source: patient.drug.drugrecurreadministration in the section 9 sample, retrieved 2026-10-29.

10 - Special populations: pregnancy, children, and older adults

Pregnancy exposure: 220 reports (0.3% of all Semaglutide primary-suspect reports); 186 of them (84.5%) flagged serious. Most reported events: Maternal Exposure During Pregnancy (164); Abortion Spontaneous (79); Off Label Use (33); Product Use In Unapproved Indication (32). FAERS holds no count of pregnant patients who took the drug without incident, so no risk rate can be computed and no conclusion about safety in pregnancy can be drawn from FAERS alone.

Children and adolescents (under 18): 25 reports (0.0% of all Semaglutide primary-suspect reports); 17 of them (68.0%) flagged serious. Most reported events: Fetal Exposure During Pregnancy (8); Premature Baby (4); Product Use Issue (3); Inappropriate Schedule Of Product Administration (2). Age bands are the reporter's categories (neonate, infant, child, adolescent) in patient.patientagegroup.

Older adults (elderly age group): 4,202 reports (5.8% of all Semaglutide primary-suspect reports); 1,769 of them (42.1%) flagged serious. Most reported events: Nausea (501); Diarrhea (359); Vomiting (344); Off Label Use (280). Elderly is the reporter's age-group category in patient.patientagegroup, not an exact age cutoff.

Source: OpenFDA drug/event - subsets of Semaglutide primary-suspect reports: pregnancy = reports carrying a pregnancy-exposure MedDRA Preferred Term (patient.reaction.reactionmeddrapt); pediatric = patient.patientagegroup 1-4; geriatric = patient.patientagegroup 6; serious = the report's serious flag, retrieved 2026-10-29.

Pregnancy outcome terms within the pregnancy subset: Premature Baby (6); Low Birth Weight Baby (1); Abortion Spontaneous (79); Congenital Anomaly (2); Fetal Growth Restriction (3); Stillbirth (1). Source: OpenFDA drug/event - MedDRA Preferred Term counts within the pregnancy-exposure subset defined above, retrieved 2026-10-29.

Signal statistics inside the special populations - ROR for each subset's top events, computed within the subset against all other FAERS reports:

Population	Event	Reports in subset	ROR (95% CI)
Pregnancy	Maternal Exposure During Pregnancy	164	694.6 (512.8-940.8)
Pregnancy	Abortion Spontaneous	79	292.0 (221.7-384.7)
Pregnancy	Off Label Use	33	4.1 (2.8-5.9)
Pediatric	Fetal Exposure During Pregnancy	8	121.0 (52.2-280.4)
Pediatric	Premature Baby	4	132.1 (45.3-384.8)
Pediatric	Product Use Issue	3	15.2 (4.5-50.6)
Older adults	Nausea	501	3.5 (3.2-3.8)
Older adults	Diarrhea	359	3.0 (2.7-3.3)
Older adults	Vomiting	344	3.9 (3.5-4.4)

Source: calculated by the author from OpenFDA drug/event counts - 2x2 tables of each subset vs all other reports in the snapshot, retrieved 2026-10-29. Subset RORs describe reporting inside that population; small counts make intervals wide.

11 - Coverage and limitations: what this assessment includes, and what FAERS cannot support

Assessment factor	Status in this dossier
Demographics (age group, sex, country)	Included - section 5; sampled median age and weight in section 9

Assessment factor	Status in this dossier
Events by patient sex	Included - section 5
Dosage form	Included - section 9 (record-level sample)
Route of administration	Partial - section 9: numeric route codes exactly as recorded (meanings are inconsistent across FAERS reporting eras, so they are not relabeled); dosage form is the reliable route guide
Dose	Included - section 9: dose text verbatim as recorded, plus parsed daily-dose bands where the text is unambiguous (parsed share stated)
Treatment duration	Included - section 9 (sampled, where both therapy dates were recorded)
Time to onset of the event	Not computable - FAERS carries no reliable structured onset date per reaction
Indication (reason for use)	Included - section 7
Concomitant medicines	Included - section 7
Pregnancy	Included - section 10, with limits stated there
Children and adolescents	Included - section 10
Older adults	Included - sections 5 and 10
Dechallenge / rechallenge	Partial - section 9: action taken with the drug (withdrawn / dose reduced / unchanged) and rechallenge recurrence tallied from the record-level sample with coverage stated; full-population dechallenge coding is too inconsistent to aggregate
Comorbidities	Not available - FAERS has no structured comorbidity record
Incidence / true risk	Not computable - FAERS has no count of patients exposed without an event; report counts and reporting odds are not risks

Source: this matrix is compiled from the OpenFDA/FAERS field dictionary for the fields named in each section's source line, checked against this drug's retrieved records on the generation date.

Method and limits. Every count in this dossier is an OpenFDA query over FAERS public data with the drug coded primary suspect; each table names its exact source fields. FAERS cannot yield incidence or risk, contains duplicates and incomplete reports, and is subject to stimulated reporting. Disproportionality statistics are calculated by the author from those counts. Signals here are hypotheses for further study, not conclusions. Prepared independently by Navindra Ramdeen, DO.

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