



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 Tirzepatide.

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.**

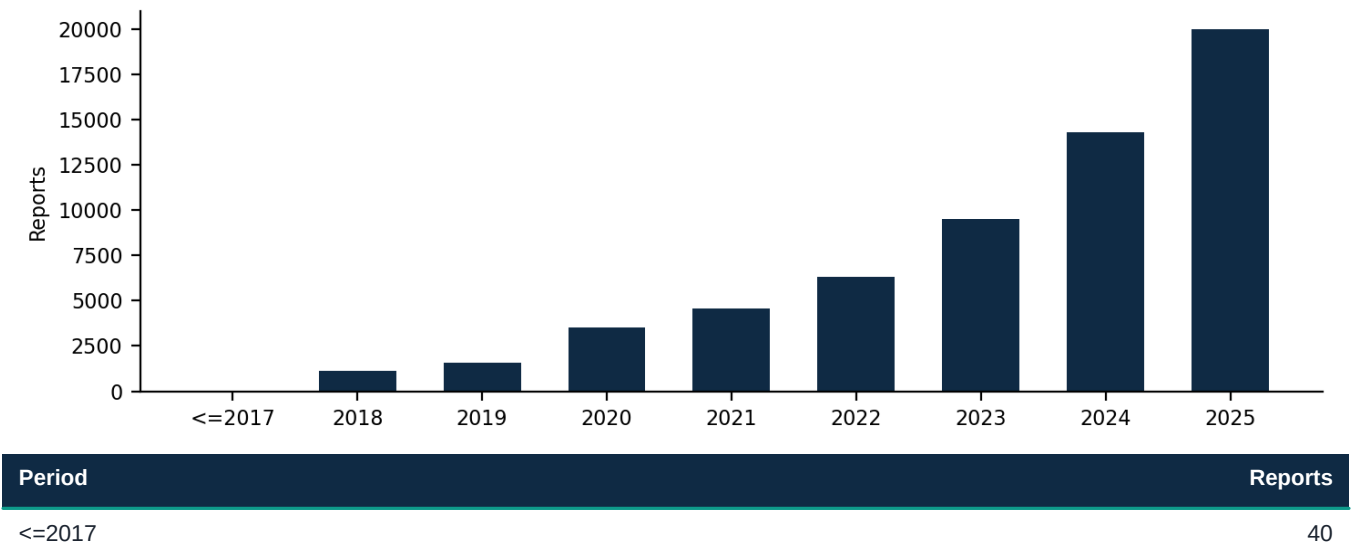
72,856	49.5%	160,201	30 Jun 2026
REPORTS - SEMAGLUTIDE AS PRIMARY SUSPECT	OF REPORTS FLAGGED SERIOUS	COMPARATOR - TIRZEPATIDE	LATEST REPORT IN THIS SNAPSHOT

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 17.6% for the comparator. Read the gap as a difference in reporting mix and product history, not a head-to-head safety verdict.

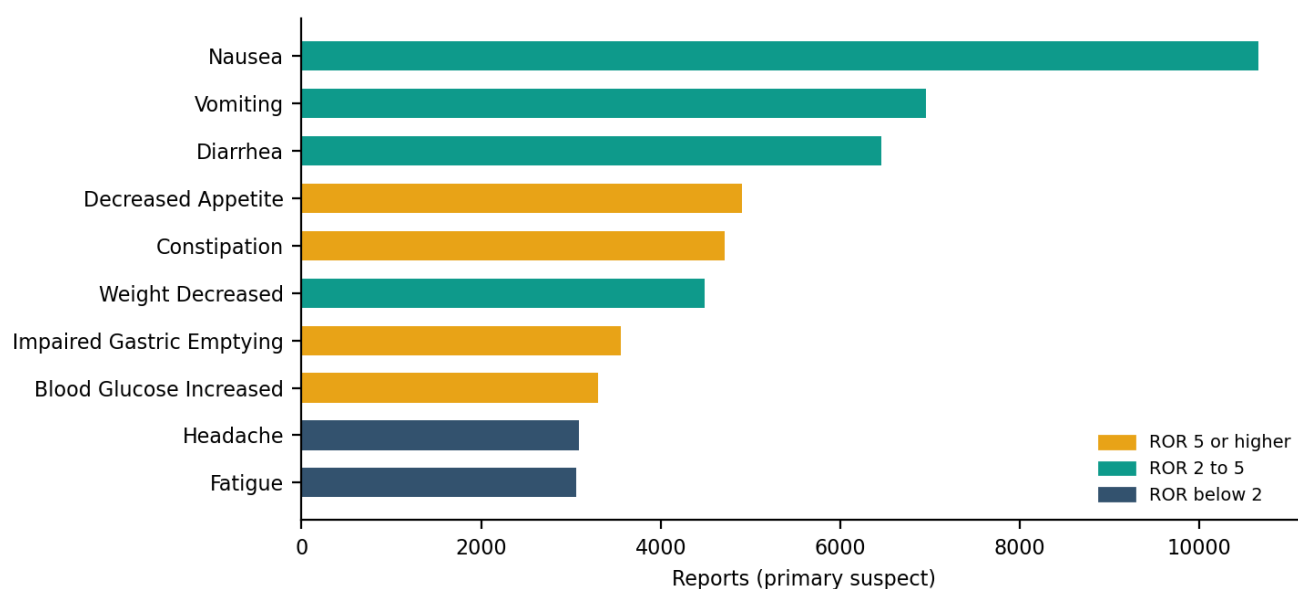
1 - Reporting trend



Period	Reports
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.

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%

Preferred Term	Reports	Share
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
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.

4 - Serious outcomes

Outcome flag	Reports	Share
Death	1,267	1.7%
Life-threatening	1,326	1.8%
Hospitalization	14,279	19.6%

Outcome flag	Reports	Share
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: 17.6% of 160,201 reports; death share: 0.6%.

5 - Who reports, and who is affected

Reporter type	Share	Patient sex	Share
Consumer / non-health professional	70.2%	Female	58.0%
Physician	15.0%	Male	32.4%
Other health professional	9.5%	Not specified	0.0%
Pharmacist	3.7%		
Lawyer	1.3%		

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

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.

6 - Severity spotlight: the five most common clinical events

Preferred Term	Reports	Flagged serious	Death flagged
Nausea	10,663	46.0%	0.8%
Vomiting	6,958	61.5%	1.2%

Preferred Term	Reports	Flagged serious	Death flagged
Diarrhea	6,454	53.8%	1.0%
Decreased Appetite	4,901	39.3%	1.0%
Constipation	4,718	51.9%	0.6%

Source: OpenFDA drug/event — for each event, the share of Semaglutide primary-suspect reports carrying that MedDRA term that are also flagged serious (serious = 1) or death (seriousnessdeath = 1), retrieved 2026-10-29. These are reporting proportions, not fatality 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.

8 - Comparator snapshot

Comparator Preferred Term	Reports	Share
Incorrect Dose Administered	29,668	18.5%
Nausea	17,064	10.7%
Injection Site Pain	13,903	8.7%

Comparator Preferred Term	Reports	Share
Diarrhea	9,982	6.2%
Extra Dose Administered	9,608	6.0%

Source: OpenFDA drug/event — Tirzepatide: 160,201 primary-suspect reports, serious share 17.6%, retrieved 2026-10-29. Shown for context only; different reporting histories make direct safety comparisons invalid.

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
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

Recorded dose	Records
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.

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.

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
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	Partial - section 9: dose text verbatim as recorded; FAERS dose is free text and cannot be reliably normalized or averaged
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

Assessment factor	Status in this dossier
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	Not reported - recorded too inconsistently in FAERS for aggregate figures to be trustworthy
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.