

FDA Adverse Events Reports (FAERS) Summary for GOSERELIN

These tables and charts are based on 5,621 total reports for GOSERELIN (GOSERELIN) received by the FDA Adverse Event Reporting System (FAERS) from 2004 through April 28, 2026.

This FAERS total includes 5,598 pharmaceutical company-submitted and non-U.S. FAERS reports and 23 U.S. consumer or healthcare provider-submitted MedWatch reports. For a separate summary of the 23 U.S. reports filed via the FDA MedWatch voluntary reporting system, view our FDA MedWatch GOSERELIN summary report. (See notes section below for explanation of FDA's mandatory and voluntary reporting system.)

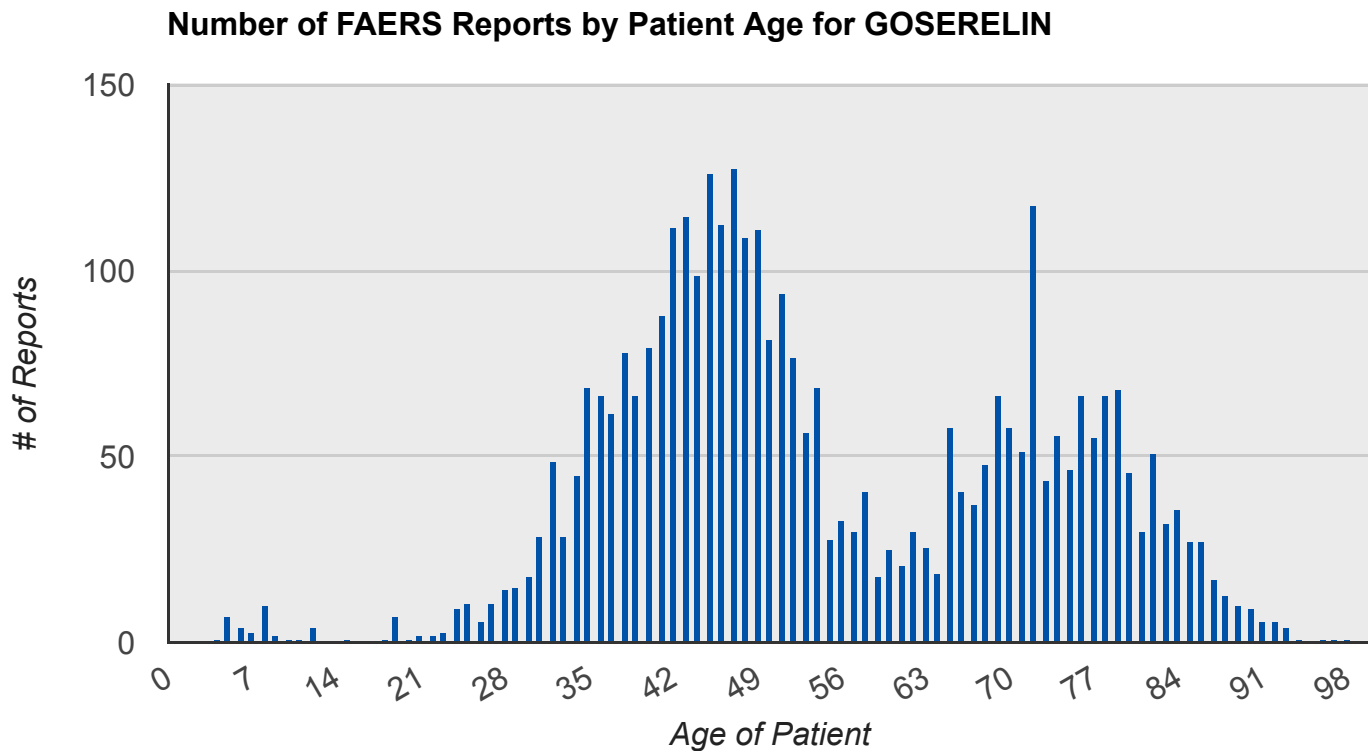
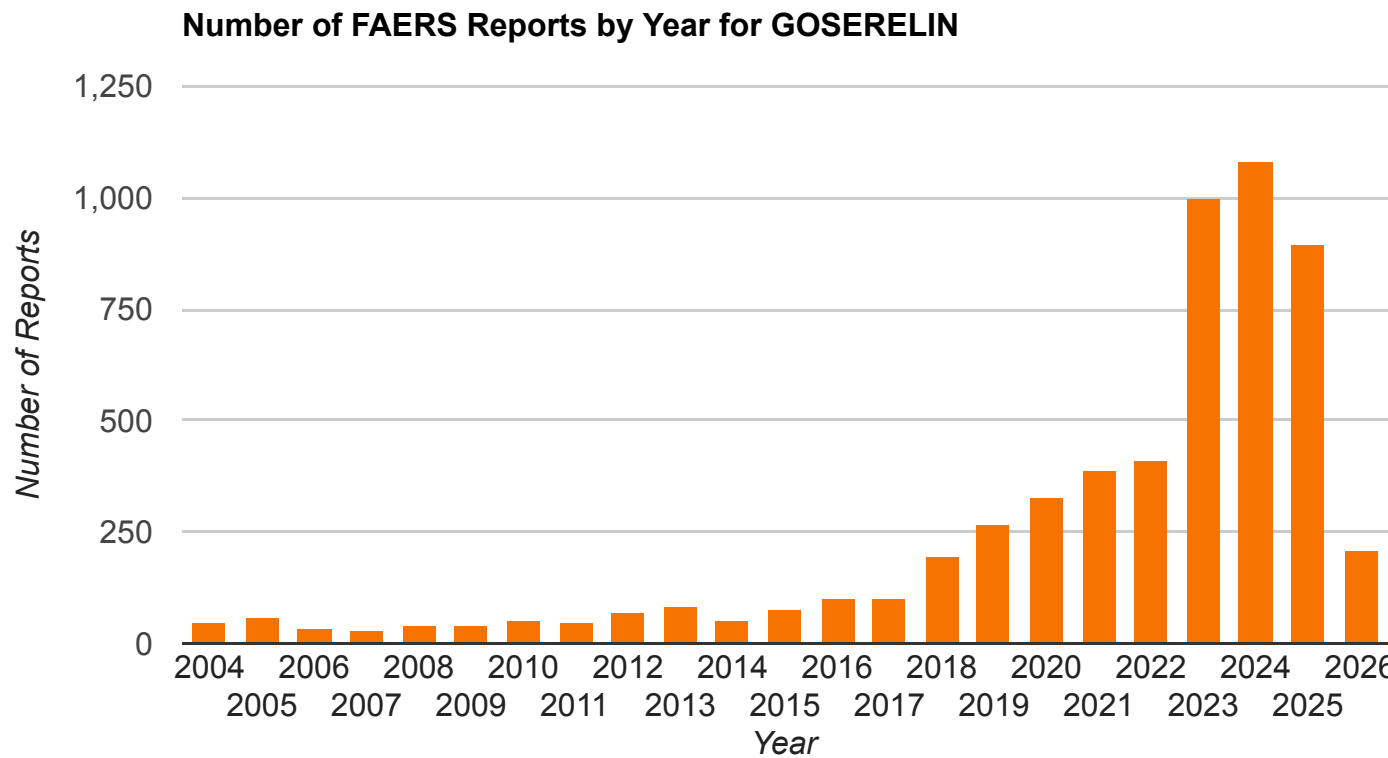
Top 20 Adverse Effects Associated with GOSERELIN (reported in FAERS Database)

	Side Effect	# of FDA Reports
1	CANCER PROGRESSION	640
2	LOW WHITE BLOOD CELL COUNTS	464
3	FATIGUE	449
4	METASTASES TO BONE	363
5	DEATH	326
6	DIARRHEA	297
7	NAUSEA	288
8	METASTASES TO LIVER	280
9	LACK OF STRENGTH AND ENERGY (ASTHENIA)	279
10	OFF LABEL USE	250
11	ANAEMIA	219
12	PAIN	200
13	SHORTNESS OF BREATH	197
14	DRUG INEFFECTIVE	185
15	BONE MARROW SUPPRESSION	180
16	JOINT PAIN	175
17	HEADACHE	172
18	DISEASE PROGRESSION	167
19	WHITE BLOOD CELL COUNT DECREASED	159
20	BREAST CANCER METASTATIC	158

Show More Reactions (20)

Latest Known Outcomes for Reactions Reported for GOSERELIN

	Latest Known Outcome for Reported Reactions	Number of Cases
1	Unknown Outcome	3036
2	Patient recovered	1521
3	Patient is recovering/symptoms resolving	1044
4	Patient has not recovered/symtoms have not resolved	921
5	Patient died	552
6	Patient has recovered but has consequent health issues	83



Search all MedWatch and FAERS by keyword:



GOSERELIN Total Reports

Male	Female	Unknown	Total
1685	2433	1503	5,621

Top Countries Reporting

Country	Number of Reports
1 Canada	556
2 China	551
3 United Kingdom	500
4 United States	472
5 Australia	313
6 Netherlands	274
7 EU	250
8 Japan	244
9 Portugal	150
10 Spain	146

Outcomes for Reports

Serious: 5320

Not Serious: 301

Note: A serious outcome means the adverse event resulted in death, a life threatening condition, hospitalization, disability, congenital anomaly, or other serious condition.

Top Indications

Prostate cancer

Product used for unknown indication

Breast cancer metastatic

Breast cancer

CANCER MALIGNANT

Top Companies Reporting

ALEXION PHARMACEUTICALS

TERSERA THERAPEUTICS

Safety-Related FDA Updates

ZOLADEX (GOSERELIN ACETATE) Rx Drug:

Risk of severe cutaneous adverse reactions (SCARs), Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS); Safety-related Labeling Changes

Have experience (good or bad) with ZOLADEX? Rate ZOLADEX at Ask a Patient.

For serious adverse events, report them to the FDA by contacting the drug manufacturer or report directly through the MedWatch voluntary reporting form.

Notes

This report, created by AskaPatient.com, is derived from the cases for GOSERELIN reported to the United States Food and Drug Administration (FDA) FDA Safety Information and Adverse Event Reporting System (FAERS) and obtained from Open FDA. Data was last updated with reports received through April 28, 2026.

This summary includes ALL reports where the drug is a "primary OR secondary OR suspected interacting" drug. Typically, reports are filed for the most serious type or "event" and do not represent incidental or minor side effects. The majority of these reports are mandatory reports submitted by pharmaceutical companies, who receive complaints from consumers. The reactions, side effects, or "adverse events," represent up to the 20 most frequently occurring events in the database for a drug related to the event. This report also features counts of latest known outcomes associated with reported side effects, but does not provide the specific outcomes for specific adverse events.

Adverse Event Reports are submitted to the FAERS database by pharmaceutical companies (mandatory reporting is required by manufacturers, distributors, or importers). Health care providers such as doctors (voluntary reporting), and patients themselves (voluntary reporting) report to the FDA directly through the MedWatch program. Those MedWatch reports are coded and included in the FAERS database. This report mainly consists of the mandatory reports, because the MedWatch reports are a small percentage (3 - 5%) of total reports. Link to the MedWatch summary report at the top of the page for a summary of the directly reported (voluntary) adverse events for this drug.The number of reports included here might differ somewhat from the number of reports in the downloadable quarterly FAERS reports and in the online FAERS dashboard, due to lags in reporting, drug name differences, duplicates, and other factors. Open FDA states that it only includes the most recent version of a case report. It also adds the disclaimer: "Do not rely on openFDA to make decisions regarding medical care. While we make every effort to ensure that data is accurate, you should assume all results are unvalidated."

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Zoladex Hair Loss



FDA uses the "MedDRA" classification system to describe reported adverse reactions. MedDRA is a standardized medical terminology that facilitates sharing of regulatory information internationally. In some cases, "patient friendly" terms for the layman designated by MedDRA have been substituted for medical jargon. Please contact us with questions or comments about this report.

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