

FDA Adverse Events Reports (FAERS) Summary for ELIGARD

These tables and charts are based on 45,918 total reports for ELIGARD (LEUPROLIDE ACETATE) received by the FDA Adverse Event Reporting System (FAERS) from 2004 through April 28, 2026.

This FAERS total includes 45,456 **pharmaceutical company-submitted and non-U.S.** FAERS reports and 462 **U.S. consumer or healthcare provider-submitted** MedWatch reports. For a separate summary of the 462 U.S. reports filed via the **FDA MedWatch** voluntary reporting system, view our [FDA MedWatch ELIGARD](#) summary report. (See notes section below for explanation of FDA's mandatory and voluntary reporting system.)

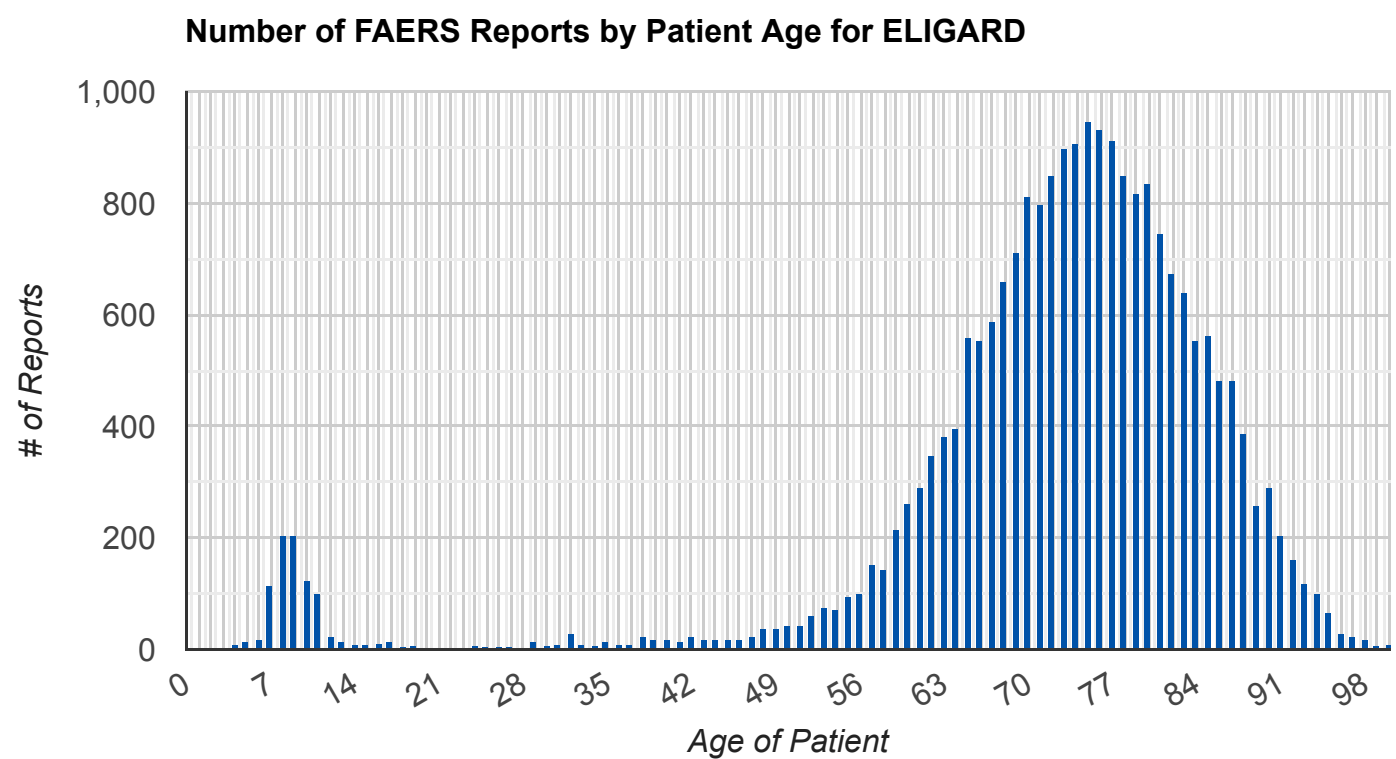
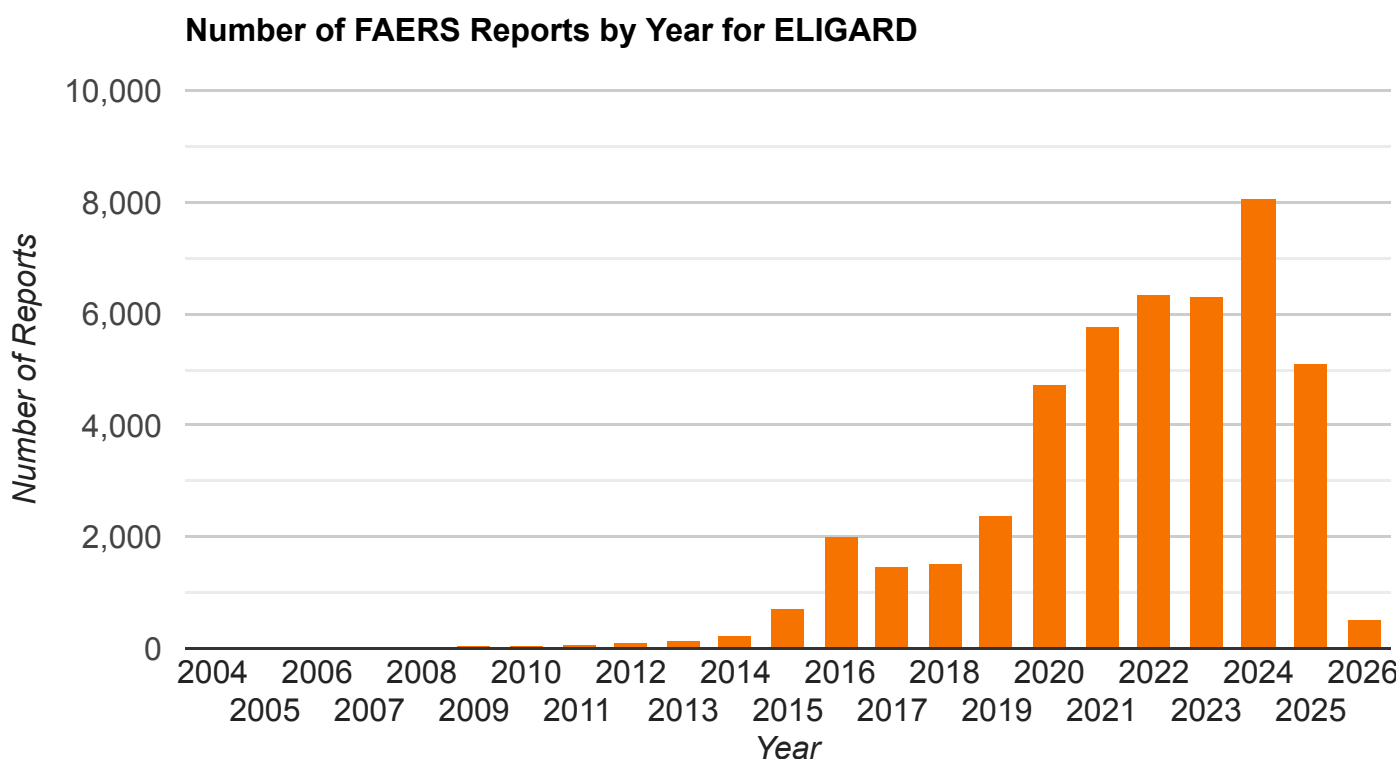
Top 20 Adverse Effects Associated with ELIGARD (reported in FAERS Database)

	Side Effect	# of FDA Reports
1	INTERCEPTED PRODUCT PREPARATION ERROR	8868
2	SYRINGE ISSUE	7728
3	HOT FLUSH	6032
4	DEATH	6014
5	DEVICE LEAKAGE	5985
6	WRONG TECHNIQUE IN PRODUCT USAGE PROCESS	5207
7	INJECTION SITE PAIN	4137
8	FATIGUE	3146
9	PROSTATIC SPECIFIC ANTIGEN INCREASED	1758
10	INTENTIONAL PRODUCT USE ISSUE	1635
11	LACK OF STRENGTH AND ENERGY (ASTHENIA)	1411
12	PROSTATE CANCER	1259
13	INJECTION SITE MASS	1241
14	OFF LABEL USE	1181
15	FALL	1166
16	INTERCEPTED MEDICATION ERROR	1122
17	DRUG INEFFECTIVE	1011
18	WEIGHT INCREASED	957
19	PRODUCT PHYSICAL CONSISTENCY ISSUE	911
20	DIZZINESS	880

Show More Reactions (20)

Latest Known Outcomes for Reactions Reported for ELIGARD

	Latest Known Outcome for Reported Reactions	Number of Cases
1	Unknown Outcome	29769
2	Patient recovered	8156
3	Patient died	7427
4	Patient has not recovered/symtoms have not resolved	7424
5	Patient is recovering/symptoms resolving	2382
6	Patient has recovered but has consequent health issues	122



Search all MedWatch and FAERS by keyword:



ELIGARD Total Reports

Male	Female	Unknown	Total
37963	1708	6247	45,918

Top Countries Reporting

Country	Number of Reports
1 Canada	16659
2 United States	11857
3 Australia	4205
4 Netherlands	4070
5 France	1813
6 Turkey	1160
7 Brazil	1081
8 Colombia	708
9 Germany	474
10 Spain	447

Outcomes for Reports

Serious: 18112

Not Serious: 27806

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

Precocious puberty

Prostate cancer metastatic

Neoplasm prostate

Top Companies Reporting

TOLMAR, INC.

TOLMAR

Safety-Related FDA Updates

FDA Approval Date: 2002-07-24

ELIGARD (LEUPROLIDE ACETATE) Rx Drug:
Risk of Suicidal and self-injurious behavior
[Safety-related Labeling Changes](#)

Have experience (good or bad) with **ELIGARD**? [Rate ELIGARD](#) 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 ELIGARD 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."

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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