



FDA Adverse Events Reports (FAERS) Summary for TRELSTAR

These tables and charts are based on 1,458 total reports for TRELSTAR (TRIPTORELIN PAMOATE) received by the FDA Adverse Event Reporting System (FAERS) from 2004 through April 28, 2026.

This FAERS total includes 1,323 **pharmaceutical company-submitted and non-U.S.** FAERS reports and 135 **U.S. consumer or healthcare provider-submitted** MedWatch reports. For a separate summary of the 135 U.S. reports filed via the **FDA MedWatch** voluntary reporting system, view our [FDA MedWatch TRELSTAR](#) summary report. (See notes section below for explanation of FDA's mandatory and voluntary reporting system.)

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

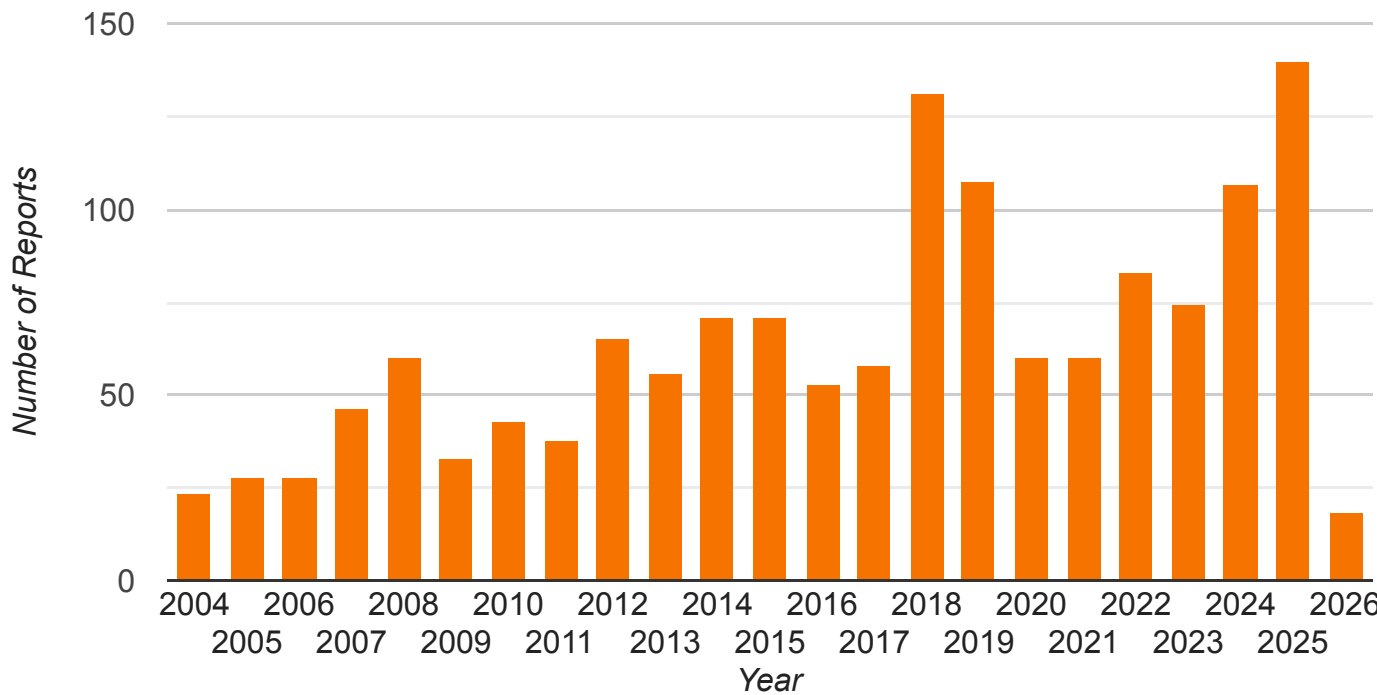
	Side Effect	# of FDA Reports
1	DEATH	119
2	FATIGUE	110
3	HOT FLUSH	89
4	LACK OF STRENGTH AND ENERGY (ASTHENIA)	72
5	INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION	72
6	OFF LABEL USE	61
7	NAUSEA	58
8	PROSTATIC SPECIFIC ANTIGEN INCREASED	55
9	PRODUCT DOSE OMISSION ISSUE	54
10	DRUG INEFFECTIVE	52
11	DIZZINESS	49
12	PAIN	46
13	JOINT PAIN	45
14	SHORTNESS OF BREATH	43
15	HEADACHE	42
16	WEIGHT DECREASED	39
17	INCORRECT DOSE ADMINISTERED	38
18	WRONG TECHNIQUE IN PRODUCT USAGE PROCESS	38
19	DECREASED APPETITE	37
20	SYRINGE ISSUE	36

Show More Reactions (20)

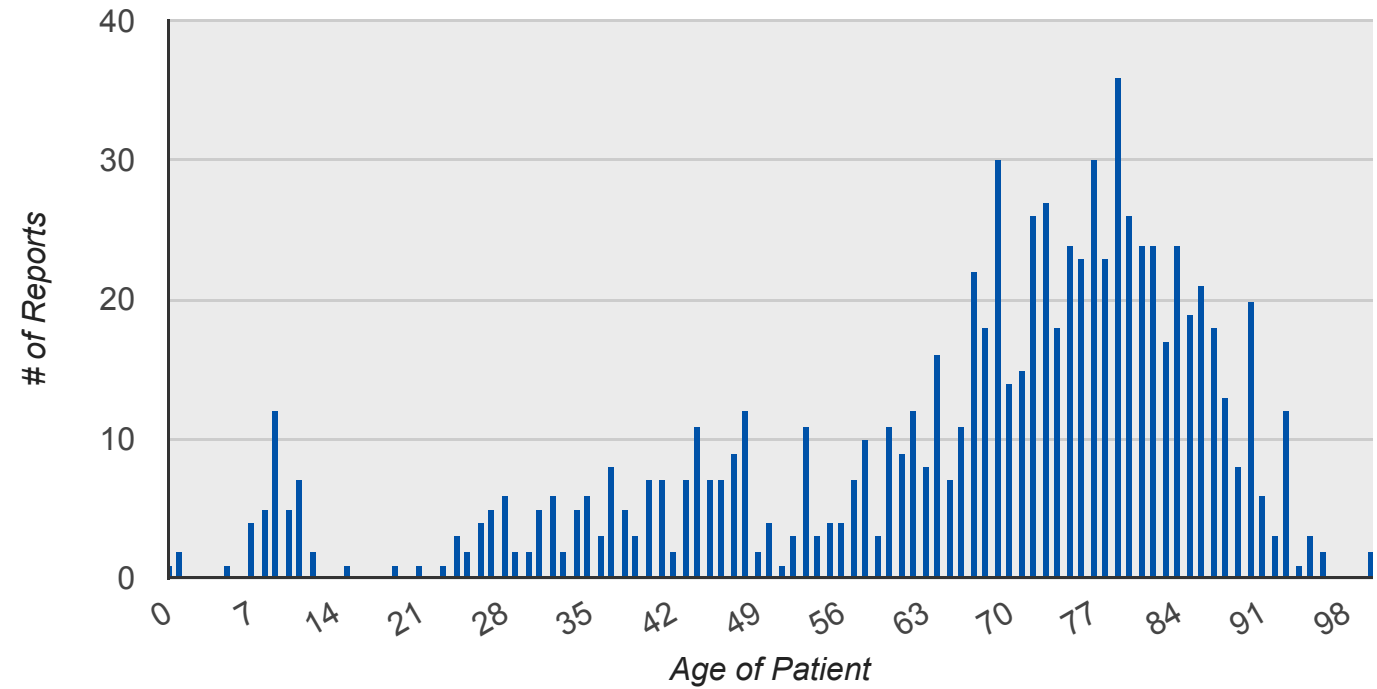
Latest Known Outcomes for Reactions Reported for TRELSTAR

	Latest Known Outcome for Reported Reactions	Number of Cases
1	Unknown Outcome	662
2	Patient has not recovered/symtoms have not resolved	285
3	Patient recovered	232
4	Patient died	119
5	Patient is recovering/symptoms resolving	83
6	Patient has recovered but has consequent health issues	10

Number of FAERS Reports by Year for TRELSTAR



Number of FAERS Reports by Patient Age for TRELSTAR



Search all MedWatch and FAERS by keyword:



TRELSTAR Total Reports

Male	Female	Unknown	Total
976	309		1,458

Top Countries Reporting

	Country	Number of Reports
1	United States	798
2	Canada	196
3	France	30
4	Germany	16
5	Switzerland	12
6	Puerto Rico	10
7	United Kingdom	7
8	Spain	5
9	Italy	5
10	Netherlands	5

Outcomes for Reports

Serious: 936

Not Serious: 522

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

Top Companies Reporting

VERITY PHARMACEUTICALS INC.

VERITY PHARMACEUTICALS

Safety-Related FDA Updates

FDA Approval Date: 2000-06-15

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 AskPatient.com, is derived from the cases for TRELSTAR 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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