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**The FDA Safety Information and
Adverse Event Reporting Program**

MedWatch Online Voluntary Reporting Form

Welcome

What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
 - Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
 - Medical devices (including in vitro diagnostic products)
 - Combination products
 - Special nutritional products (dietary supplements, infant formulas, and medical foods)
 - Cosmetics
 - Foods/beverages (including reports of serious allergic reactions)
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What Not to Report to MedWatch:

- Vaccines: Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at <https://vaers.hhs.gov/esub/step1> (<https://vaers.hhs.gov/esub/step1>)
- Investigational (study) drugs
(<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf>): Report investigational (study) drug adverse events as required in the study protocol and send to the address and contact person listed in the study protocol.
- Mandatory reporting by regulated industry:

- [Drugs and Biologics \(http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085692.htm\)](http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085692.htm)
- [Devices \(http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm\)](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm)
- [Reporting on Dietary Supplements \(http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/default.htm\)](http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/default.htm)
- [Reporting on Veterinary Medicine Products \(http://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm\)](http://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm)
- [Reports FDA Does Not Handle \(http://www.fda.gov/Safety/ReportaProblem/QuestionsandAnswersProblemReporting/default.htm#problems\)](http://www.fda.gov/Safety/ReportaProblem/QuestionsandAnswersProblemReporting/default.htm#problems) (e.g. CPSC, FTC, State Health Departments) and Where to Send Them

Begin Report As a:

Health Professional

Consumer/Patient

Frequently Asked Questions







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Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players \(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ViewingFiles/default.htm\)](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ViewingFiles/default.htm).

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