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Drugs

Drug Safety Podcasts

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Resources for You

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- FDA Drug Info Rounds Video
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- Drug Safety Communications



Listen to Drug Safety Communications

The FDA Drug Safety Podcasts are produced by FDA's Center for Drug Evaluation and Research (CDER). They provide emerging safety information about drugs in conjunction with the release of Drug Safety Communications.

Latest Drug Safety Podcasts

Title	Date	Link to Podcast	Link to Transcript
FDA Drug Safety Podcast: FDA warns of serious immune system reaction with seizure and mental health medicine lamotrigine (Lamictal)	April 25, 2018	Listen <i>Run Time: 00:3:00</i>	Transcript

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4/30/2018

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FDA Drug Safety Communication

FDA review finds additional data supports the potential for increased long-term risks with antibiotic clarithromycin (Biaxin) in patients with heart disease

Safety Announcement

[02-22-2018] The U.S. Food and Drug Administration (FDA) is advising caution before prescribing the antibiotic clarithromycin (Biaxin) to patients with heart disease because of a potential increased risk of heart problems or death that can occur years later. Our recommendation is based on our review of the results of a 10-year follow-up study¹ of patients with coronary heart disease from a large clinical trial² that first observed this safety issue.

As a result, we have added a new warning about this increased risk of death in patients with heart disease, and advised prescribers to consider using other antibiotics in such patients. We have also added the study results to the clarithromycin drug labels. As part of FDA's usual ongoing safety monitoring of drugs, we are continuing to monitor safety reports in patients taking clarithromycin.

Health care professionals should be aware of these significant risks and weigh the benefits and risks of clarithromycin before prescribing it to any patient, particularly in patients with heart disease and even for short periods, and consider using other available antibiotics. Advise patients with heart disease of the signs and symptoms of cardiovascular problems, regardless of the medical condition for which you are treating them with clarithromycin.

Patients should tell your health care professionals if you have heart disease, especially when you are being prescribed an antibiotic to treat an infection. Talk to them about the benefits and risks of clarithromycin and any alternative treatments. Do not stop taking your heart disease medicine

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Division of Drug Information - DDI

Division Director: [Mary Kremzner, Pharm.D., M.P.H.](#)
Deputy Director: [Catherine Chew, Pharm.D.](#)
CDER Small Business and Industry Assistance (SBIA) Program Director: [Brenda Stodart, Pharm.D.](#)

OUR MISSION
 The mission of DDI is to optimize CDER's educational and communication efforts to our global community. We accomplish this by building effective internal and external interactions to provide timely, accurate, and useful information through both traditional and social media channels. We support the Agency's mission to promote and protect public health.

WHAT WE DO
 DDI responds to public inquiries on human drug products from domestic and international consumers, health care professionals, regulated industry, academia, law enforcement, insurance companies, FDA colleagues, as well as other government agencies. DDI is staffed with a team of pharmacists and other health care professionals who provide expert advice and guidance regarding all aspects of CDER activities. We provide communication from CDER to health care audiences through social media including Facebook, Twitter, and LinkedIn, and through electronic media including podcasts, videos, and subscription email updates.

Our CDER SBIA Program assists regulated domestic and international pharmaceutical businesses seeking information on the development and regulation of human drug products. We maintain the Drug Safety Labeling Changes (SLC) database which provides timely updates of approved safety labeling changes publicly available in downloadable/searchable formats. We also facilitate voluntary reporting to MedWatch by consumers and health care professionals on behalf of CDER.

In 2016 DDI responded to:
 44,806 phone calls -- 17,029 emails -- 784 letters

PROGRAMS AND SERVICES

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Information for Consumers (Drugs)

- Educational Resources: Free Drug-Related Publications
- JumpStarting Drug Review
- Questions & Answers
- Buying & Using Medicine Safely
- Tips for Seniors
- Tips for Parents
- En Español
- Prescription Drug Advertising

Drugs

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Think It Through: Managing the Benefits and Risks of Medicines

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For many people, taking medication is a regular part of their daily routine, and these medicines are relied upon to treat disease and improve health. Although medicines can make you feel better and help you get well, it's important to know that all medicines, both prescription and over-the-counter, have risks as well as benefits

The benefits of medicines are the helpful effects you get when you use them, such as lowering blood pressure, curing infection, or relieving pain. The risks of medicines are the chances that something unwanted or unexpected could happen to you when you use them. Risks could be less serious things, such as an upset stomach, or more serious things, such as liver damage. Here are some tips from the Food and Drug Administration and some of its public health partners to help you weigh the risks and benefits when you make decisions about the medicines you use.

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Drugs

Tips for Seniors

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Resources for You

- BeSafeRx: Know Your Online Pharmacy

As you get older you may be faced with more health conditions that you need to treat on a regular basis. It is important to be aware that more use of medicines and normal body changes caused by aging can increase the chance of unwanted or maybe even harmful drug interactions. The more you know about your medicines and the more you talk with your health care professionals, the easier it is to avoid problems with medicines.

Information for Seniors

- As You Age...A Guide to Aging, Medicines, and Alcohol.
- As You Age: You and Your Medicines
- Medicines and You: A Guide for Older Adults Medicines and You: A Guide for Older Adults
- Stop -- Learn -- Go -- Tips for Talking with Your Pharmacist to Learn How to Use Medicines Safely
- MedlinePlus: Seniors' Health

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Medication Guides

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- Drug Alerts and Statements
- Medication Guides**
- Drug Safety Communications
- Drug Shortages
- Postmarket Drug Safety Information for Patients and Providers
- Information by Drug Class
- Medication Errors
- Drug Safety Podcasts
- Safe Use Initiative
- Drug Recalls

Drugs@FDA and DailyMed also contain medication guides as part of drug labeling.

Get email alerts when the Medication Guides page is updated.

Medication Guides are paper handouts that come with many prescription medicines. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.

FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that:

- certain information is necessary to prevent serious adverse effects
- patient decision-making should be informed by information about a known serious side effect with a product, or
- patient adherence to directions for the use of a product are essential to its effectiveness.

Information Update (3/2017)

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For Patients

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- new product approvals
- FDA announcements
- ways to get involved
- public meetings
- safety information
- tobacco products
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Spotlight

- FDA In Brief: FDA launches mobile app to increase access to information about drugs
- Listen to webinars with FDA experts
- Learn About the FDA Patient Representative Program
- Statement from FDA Commissioner on FDA's efforts to enhance the patient perspective and experience in [drug development](#)

FDA Patient Network Newsletter
Read the latest edition - April 25, 2018

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