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The FDA Drug Safety Communications posted on this web page are intended to provide important information about new safety issues with the medicines health care professionals are prescribing and patients are taking.

All drugs carry risks so FDA continues to monitor their safety after they are approved. When we learn information about a potential new safety issue, we may take actions such as requiring changes to the prescribing information. We may also release a Drug Safety Communication or other public communications to alert patients and health care professionals about the issue so they can make more informed decisions about treatment.

To receive FDA approval, the benefits of a drug must outweigh its risks or side effects. To determine if a new drug should be approved, a team of FDA physicians and other scientists reviews evidence a drug company submits as part of its drug application. This evidence includes data from clinical trials. These trials typically include a limited number of patients that meet very specific health criteria and are often conducted on a short-term basis. Widespread or long-term use by patients may uncover side effects that were not discovered during clinical trials, so FDA continues to monitor all medicines after they are approved.

You can get new safety information on medicines you're prescribing or taking by signing up for email alerts on types of drugs or medical specialties of interest to you.

Spanish-language versions of the Drug Safety Communications can be found by visiting our Drug Safety Communications in Spanish page.

Current Drug Safety Communications

- 10/15/2020 FDA recommends avoiding use of NSAIDs in pregnancy at 20 weeks or later because they can result in low amniotic fluid
- 9/24/2020 FDA warns about serious problems with high doses of the allergy medicine diphenhydramine (Benadryl)
- 9/23/2020 FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class
- 8/26/2020 FDA removes Boxed Warning about risk of leg and foot amputations for the diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR)
- 7/23/2020 FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder
- 3/4/2020 FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis

See More

Previous Drug Safety Communications

- 2020 Drug Safety Communications
- 2019 Drug Safety Communications
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- 2017 Drug Safety Communications
- 2016 Drug Safety Communications
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- 2013 Drug Safety Communications
- 2012 Drug Safety Communications
- 2011 Drug Safety Communications
- 2010 Drug Safety Communications

Additional Resources for You

- Development & Approval Process (Drugs)
- How Drugs are Developed and Approved
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Frequently Asked Questions about the FDA Drug Approval Process
- CDER Conversation: CDER's Drug Safety Communications: Ensuring postmarket safety
- Drugs@FDA: FDA-Approved Drugs

FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis

Risks may include suicidal thoughts or actions

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3-4-2020 FDA Drug Safety Communication

- **What safety concern is FDA announcing?**
- **What is FDA doing?**
- **What is montelukast and how can it help me?**
- **What should patients and parents/caregivers do?**
- **What should health care professionals do?**
- **What did FDA find?**
- **What is my risk?**
- **How do I report side effects from montelukast?**
- **Facts about Montelukast**
- **Additional Information for Patients and Parents/Caregivers**
- **Additional Information for Health Care Professionals**
- **Data Summary**
- **References**

en Español

Drug Safety Communication (PDF - 68 KB)

Related Information

- Allergy Relief for Your Child
- Medline Plus: Asthma
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines
- Advisory Committees: Critical to the FDA's Product Review Process

Contact FDA

For More Info
855-543-DRUG (3784) and press 4
druginfo@fda.hhs.gov

Report a Serious Problem to MedWatch
Complete and submit the report Online.
Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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3-4-2020 FDA Drug Safety Communication

What safety concern is FDA announcing?

The U.S. Food and Drug Administration (FDA) is strengthening existing warnings about serious behavior and mood-related changes with montelukast (Singulair and generics), which is a prescription medicine for asthma and allergy.

We are taking this action after a review of available information led us to reevaluate the benefits and risks of montelukast use. Montelukast prescribing information already includes warnings about mental health side effects, including suicidal thoughts or actions; however, many health care professionals and patients/caregivers are not aware of the risk. We decided a stronger warning is needed after conducting an extensive review of available information and convening a panel of outside experts, and therefore determined that a *Boxed Warning* was appropriate.

Because of the risk of mental health side effects, the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with other medicines. For allergic rhinitis, also known as hay fever, we have determined that montelukast should be reserved for those who are not treated effectively with or cannot tolerate other allergy medicines. For patients with asthma, we recommend that health care professionals consider the benefits and risks of mental health side effects before prescribing montelukast.

What is FDA doing?

What is montelukast and how can it help me?

What should patients and parents/caregivers do?

What should health care professionals do?

What did FDA find?

What is my risk?

How do I report side effects from montelukast?

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- FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder 7/23/2020
- FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems 4/24/2020
- FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis 3/4/2020
- FDA requests the withdrawal of the weight-loss drug Belviq, Belviq XR (lorcaserin) from the market 2/13/2020
- FDA strengthens warning that untreated constipation caused by schizophrenia medicine clozapine (Clozaril) can lead to serious bowel problems 1/28/2020
- Safety clinical trial shows possible increased risk of cancer with weight-loss medicine Belviq, Belviq XR (lorcaserin) 1/14/2020

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