FDA warns about serious heart problems with high doses of the antidiarrheal medicine loperamide (Imodium), including from abuse and misuse

FDA Drug Safety Communication

The U.S. Food and Drug Administration (FDA) is warning that taking higher than recommended doses of the common over-the-counter (OTC) and prescription diarrhea medicine loperamide (Imodium), including through abuse or misuse of the product, can cause serious heart problems that can lead to death. The risk of these serious heart problems, including abnormal heart rhythms, may also be increased when high doses of loperamide are taken with several kinds of medicines that interact with loperamide (see Examples of Drugs that Can Potentially Interact with Loperamide).

The majority of reported serious heart problems occurred in individuals who were intentionally misusing and abusing high doses of loperamide in attempts to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria. We continue to evaluate this safety issue and will determine if additional FDA actions are needed.

Patients and consumers should only take loperamide in the dose directed by their health care professionals or according to the OTC Drug Facts label. Do not use more than the dose prescribed or listed on the label, as doing so can cause severe heart rhythm problems or death. If your diarrhea lasts more than 2 days, stop taking loperamide and contact your health care professional. Seek medical attention immediately by calling 911 if you or someone taking loperamide experiences any of the following:

- Fainting
- Rapid heartbeat or irregular heart rhythm
- Unresponsiveness, meaning that you can't wake the person up or the person doesn't answer or react normally

Ask a pharmacist or your health care professional if you are not sure how much loperamide to take, how often to take it, or whether a medicine you are taking may interact with loperamide. Always tell your health care professionals about all the medicines you are taking, including OTC medicines (see Examples of Drugs that Can Potentially Interact with Loperamide).

Loperamide is approved to help control symptoms of diarrhea, including Travelers' Diarrhea. The maximum approved daily dose for adults is 8 mg per day for OTC use and 16 mg per day for prescription use. It is sold under the OTC brand name Imodium A-D, as store brands, and as generics.

In the 39 years from when loperamide was first approved in 1976 through 2015, FDA received reports* of 48 cases of serious heart problems associated with use of loperamide. This number includes only reports submitted to FDA, so there are likely additional cases about which we are unaware. Thirty-one of these cases resulted in hospitalizations, and 10 patients died. More than half of the 48 cases were reported after 2010. The serious heart problems occurred mostly in patients who were taking doses that were much higher than recommended. In other cases, patients were taking the recommended dose of loperamide, but they were also taking interacting medicines, causing an increase in loperamide levels. Additional cases of serious heart problems associated with the use of loperamide were reported in the medical literature.[1-9] Cases reported to FDA and in the medical literature indicate that individuals are taking significantly high doses of loperamide in situations of both misuse and abuse, often attempting to achieve euphoria or self-treat opioid withdrawal. They are also combining loperamide with interacting drugs in attempts to increase these effects.

We urge patients, consumers, and health care professionals to report side effects involving loperamide or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS).

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.