

Imodium Safety Communication

June 7, 2016

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.

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. In cases of abuse, individuals often use other drugs together with loperamide in attempts to increase its absorption and penetration across the blood-brain barrier, inhibit loperamide metabolism, and enhance its euphoric effects.

Health care professionals should be aware that use of higher than recommended doses of loperamide can result in serious cardiac adverse events. Consider loperamide as a possible cause of unexplained cardiac events including QT interval prolongation, Torsades de Pointes or other ventricular arrhythmias, syncope, and cardiac arrest. If loperamide toxicity is suspected, promptly discontinue the drug and start necessary therapy. If loperamide ingestion is suspected, measure blood levels, which may require specific testing. For some cases of Torsades de Pointes in which drug treatment is ineffective, electrical pacing or cardioversion may be required. 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 diarrhea lasts more than 2 days, stop taking loperamide and contact a 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

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓ Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓ Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at
<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.]

Source: <http://www.fda.gov/Drugs/DrugSafety/ucm504617.htm>