

Imodium® (loperamide) – Safety communication

- On January 30, 2018, the [FDA announced](#) that they are limiting the number of doses per package for over-the-counter (OTC) [loperamide](#) products due to reports of serious heart problems and deaths with higher than recommended doses, primarily in individuals who are intentionally misusing or abusing the product.
- Loperamide is generically available as a prescription and OTC medication to control symptoms of diarrhea, including Travelers' Diarrhea.
- Previously, the [FDA issued](#) a safety communication about this concern in June 2016 and added warnings to the drug label of prescription loperamide and the OTC Drug Facts label. However, the FDA continues to receive reports of serious heart problems and deaths despite the previous communication and additional warning.
 - 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.
 - Some individuals are taking high doses of loperamide to treat symptoms of opioid withdrawal.
- The FDA is working with manufacturers of loperamide to use blister packs or other single dose packaging and to limit the number of doses in a package.
- Patients should only take the dose of loperamide directed by the healthcare provider or according to the OTC Drug Facts label.
 - While loperamide is safe at approved doses, when taken at much higher than recommended doses, it can lead to serious problems, including severe heart rhythm problems and death. The maximum daily dose of loperamide in adults is 8 mg per day for OTC use and 16 mg per day for prescription use.
 - If a patient is using OTC loperamide for diarrhea and symptoms persist more than 2 days, the patient should stop taking the medicine and contact his or her healthcare professional.
 - Medical attention should be sought immediately by calling 911 if the patient or someone taking loperamide experiences fainting, rapid heartbeat or irregular heart rhythm, or unresponsiveness (ie, person cannot wake up or does not answer or react normally).
- Healthcare providers should be aware that using much higher than recommended doses of loperamide can result in serious cardiac adverse events, including QT interval prolongation, torsade de pointes or other ventricular arrhythmias, syncope, and cardiac arrest.
 - If loperamide toxicity is suspected, healthcare providers should promptly discontinue the drug and start necessary therapy. For some cases of abnormal heart rhythms in which drug treatment is ineffective, electrical pacing or cardioversion may be required.

- Healthcare providers should counsel patients to take loperamide only as prescribed or according to the OTC Drug Facts label and advise patients that drug interactions with commonly used medicines may increase the risk of serious cardiac events.



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