



FDA limits packaging for anti-diarrhea medicine loperamide (Imodium) to encourage safe use

This is an update to the [FDA Drug Safety Communication: FDA warns about serious heart problems with high doses of the antidiarrheal medicine loperamide \(Imodium\), including from abuse and misuse](#) issued on June 7, 2016.

Safety Announcement

[1-30-2018] To foster safe use of the over-the counter (OTC) anti-diarrhea drug loperamide, the U.S. Food and Drug Administration (FDA) is working with manufacturers to use blister packs or other single dose packaging and to limit the number of doses in a package. We continue to receive reports of serious heart problems and deaths with much higher than the recommended doses of loperamide, primarily among people who are intentionally misusing or abusing the product, despite the addition of a warning to the medicine label and a previous communication. Loperamide is a safe drug when used as directed.

Loperamide is FDA-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. Loperamide acts on opioid receptors in the gut to slow the movement in the intestines and decrease the number of bowel movements. It is safe at approved doses, but when much higher than recommended doses are taken, it can lead to serious problems, including severe heart rhythm problems and death.

Patients and consumers should only take the dose of loperamide directed by your health care professionals or according to the [OTC Drug Facts label](#), as taking more than prescribed or listed on the label can cause severe heart rhythm problems or death. If you are using OTC loperamide and your diarrhea lasts more than 2 days, stop taking the medicine and contact your health care professional.

Seek medical attention immediately by calling 911 if you or someone taking loperamide experiences any of the following, and tell health care professionals the person has been taking loperamide:

- 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

Health care professionals should be aware that using much higher than recommended doses of loperamide, either intentionally or unintentionally, can result in serious cardiac adverse events, including QT interval prolongation, Torsades de Pointes or other ventricular arrhythmias, syncope, and cardiac arrest. 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. If loperamide toxicity is suspected, 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. Also 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.

We previously issued a [Drug Safety Communication](#) about this safety concern and added warnings about serious heart problems to the [drug label of prescription loperamide](#) and to the [Drug Facts label of OTC loperamide products](#). We are continuing to evaluate this safety issue and will update the public when more information is available.

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.

Related Information

[Loperamide \(marketed as Imodium A-D\) Information](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)