Generic Name:
Loperamide
Trade Name:
Imodium, others
Company:
Multiple companies
Notes:

To foster safe use of the OTC antidiarrhea drug loperamide, FDA is working with manufacturers to use blister packs or other single-dose packaging and to limit the number of doses in a package.

The agency continues 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 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.

Individuals should take only the dose of loperamide directed by their health professionals or according to the OTC Drug Facts label. If diarrhea lasts more than 2 days despite the use of loperamide, patients should stop taking the medicine and contact their health care provider.

Individuals should seek medical attention immediately by calling 911 if they or someone taking loperamide experiences any of the following, and tell health professionals the person has been taking loperamide: fainting, rapid heartbeat or irregular heart rhythm, and unresponsiveness (you can?t wake the person up, or the person doesn?t answer or react normally).

Health 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.

FDA previously issued a Drug Safety Communication and added warnings about serious heart problems to the drug label of prescription loperamide and to the Drug Facts label of OTC loperamide products. The agency is continuing to evaluate this safety issue and will update the public when more information is available.

Medication Monitor Categories:
Alerts and Recalls
