



Loperamide (Imodium): Drug Safety Communication - Serious Heart Problems With High Doses From Abuse and Misuse

[Posted 06/07/2016]

FDA 發布一則藥物安全警訊，濫用或誤用 loperamide 高於非處方藥物的建議劑量每天 8mg 或高於處方藥物的建議劑量每天 16mg 都可能導致不正常的心臟節律問題，這個嚴重的心臟問題也有可能是因為 loperamide 藥物交互作用造成的劑量過高，例如 gemfibrozil 與 loperamide 併用會導致 loperamide 血中濃度過高。

根據通報案例，故意濫用高劑量的 loperamide 主要是企圖自我治療鴉片類藥物造成的戒斷症狀，或嘗試達到欣快感。

建議：

醫療人員應該注意 loperamide 使用超過建議劑量可能導致嚴重不明原因的心臟問題，包括 QT 間期延長、Torsades de Pointes、或是其他的心室性心律不整、昏厥、心臟驟停。在濫用 loperamide 的案例中，有些人是企圖與其他藥物併用來增加藥物的吸收、穿透血腦障壁和抑制 loperamide 代謝進而增加欣快感的作用。一旦懷疑 loperamide 中毒，應立即停用 loperamide 並給予必要的治療，例如 Torsades de Pointes 使用藥物治療的效果有限，可能需要使用心臟起搏器或心臟整律術。

病患和消費者應該遵循醫師指示或非處方藥品的仿單服用 loperamide，如果 loperamide 服用兩天仍持續腹瀉，應該停止服用並尋求醫療人員協助。另外，如果服用後發生昏暈、心跳加速或心臟節律不規則、反應遲鈍(無法喚醒或無法正常對應)時，應該立即就醫。

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AUDIENCE: Pharmacy, Cardiology, Internal Medicine, Pain Management, Consumer

ISSUE: 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, in the FDA Drug Safety Communication).

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. FDA continues to evaluate this safety issue and will determine if additional FDA actions are needed.

BACKGROUND: 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. See the FDA Drug Safety Communication for data summary.

RECOMMENDATION: 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. 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. 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. Refer patients with opioid use disorders for treatment (see Additional Information for Health Care Professionals in the FDA Drug Safety Communication).

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