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INFORMATION FOR HEALTHCARE PROFESSIONAL

High Dosage of Loperamide and Serious Heart Problem Risks

Loperamide is a drug indicated for 18 years old or above patients suffering from non-specific acute diarrhea and chronic diarrhea with refractory inflammatory bowel disease. Early dosage of loperamide is 4 mg, followed by 2 mg each defecation. The daily dosage must not exceed 16 mg a day.

On June 7, 2016 the US FDA informed Drug Safety Communication concerning serious heart problem risks caused by misuse and abuse of a high dosage of the anti-diarrhea loperamide (Imodium). Since the FDA approved the use of loperamide in 1976 up to 2015, FDA had receive 48 case reports of serious heart problems concerning the use of loperamide. The most commonly reported heart problems are syncope (24 cases), cardiac arrest (13 cases), QT interval prolongation (13 cases), ventricular tachycardia (10 cases), and *Torsade de Pointes* (7 cases).

Most reported cases concerning heart problems involved individuals who voluntarily abused loperamide in dosages higher than recommended to self-cure symptoms of opioid withdrawal or to achieve euphoric feelings. In other cases, patients used it on recommended dosage but combined loperamide with other drugs that, due to interactions, increase the loperamide concentration. Drugs that can increase loperamide concentration through interactions in blood are, among others, cimetidine, clarithromycin, erythromycin, gemfibrozil, itraconazole, ketokonazole, quinidine, quinine, ranitidine, ritonavir.

If cardio toxicity is suspected to result from loperamide, immediately discontinue the use of loperamide and give therapy to handle and prevent heart arrhythmia or other more severe outcomes.

So far, the NADFC as the National Center of Pharmacovigilance has not received case reports involving serious heart problem risks related to the use of anti-diarrhea loperamide yet. The NADFC conveys this information to improve the healthcare professionals awareness and to become a guidance in prescribing loperamide. Healthcare professionals are advised to report adverse drug reaction to the Indonesian NADFC by using the yellow form or by making online reports to the *e-meso* sub-site (http://e-meso.pom.go.id) to provide sufficient data about

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loperamide-related cases so that the safety of products circulating in Indonesia can be evaluated and conveyed as information about drugs to patients based on the population data in Indonesia. The NADFC will continuously monitor aspect of drug safety to provide an optimum protection to the public health, and to ensure drug safety in Indonesia.