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DEPARTMENT OF VETERANS AFFAIRS
VETERANS HEALTH ADMINISTRATION
PHARMACY BENEFITS MANAGEMENT STRATEGIC HEALTHCARE GROUP,
MEDICAL ADVISORY PANEL AND
CENTER FOR MEDICATION SAFETY (VA MEDSAFE)

VAMedSAFE Bulletin: FDA Public Health Advisory on Methadone

Methadone is an effective, potent opioid analgesic that is being increasingly used for the treatment of chronic pain. In November 2006, the Food and Drug Administration (FDA) issued the following public health advisory to warn providers about the potential for death, overdose, and serious cardiac arrhythmias associated with methadone, particularly when methadone therapy is initiated, during opioid rotations / conversions, and when methadone dosage is changed. The FDA revised the product information for methadone to include an additional black box warning regarding methadone-associated deaths and other serious adverse events and to provide additional dosing recommendations.

VA MedSAFE Recommendations:

1. Before prescribing methadone, providers should familiarize themselves with the pharmacokinetics, unique pharmacologic properties, and recommendations and different strategies for dosing methadone. Information on these topics are provided at the links below.

FDA Alert / Methadone Information: http://www.fda.gov/cder/drug/infopage/methadone/default.htm

Healthcare Provider Information: http://www.fda.gov/cder/drug/InfoSheets/HCP/methadoneHCP.pdf

Revised Product Information: http://www.fda.gov/cder/foi/label/2006/006134s028lbl.pdf

Patient Information: http://www.fda.gov/cder/drug/infopage/methadone/dolophine_PI.pdf

Methadone Dosing Recommendations for Treatment of Chronic Pain:
http://vaww.pbm.va.gov/monitoring/Methadone%20Dosing%20Final%20(Rev%20081103).pdf

2. Providers who are unfamiliar with dosing methadone should seek assistance from a practitioner who has knowledge of titrating this agent. The use of methadone for pain should ideally be done in the context of an organized pain clinic or with assistance of local pain management experts, including health care providers or pharmacists, who have experience with methadone use. If such resources are not readily available and a long-acting opioid is indicated, long-acting morphine is preferred; other alternatives include oxycodone controlled-release and transdermal fentanyl.
3. Individualize methadone doses. In general, keep initial doses small, adjust conversion ratios to the previous opioid dose, and slowly (e.g., every 5 to 7 days) titrate dosage to patient response.
4. If a patient develops sedation (which may be a precursor to respiratory depression), hold or decrease the following dose of previous opioid or methadone (depending on the dosing strategy) and decrease subsequent doses and/or make dosage increments less frequently. Do not increase the dose of methadone.
5. Use additional caution with elderly patients (≥ 65 years), patients with liver, renal, or pulmonary disease, debilitated patients, and patients previously receiving high doses of opioid.
6. Closely monitor patients during methadone therapy, particularly after initiating methadone, making opioid conversions, or changing doses.
7. Advise patients on how to take methadone and not to take more than the prescribed amount of methadone without first consulting their health care provider.