

Methadone Hydrochloride (marketed as Dolophine) Information

The issues described in this communication have been addressed in product labeling, Please see Drugs@FDA.
Website: <http://www.fda.gov/Drugs/default.htm>
DOLOPHINE HYDROCHLORIDE (Brand Name Drug)

FDA ALERT [11/2006]: Death, Narcotic Overdose, and Serious Cardiac Arrhythmias

FDA has reviewed reports of death and life-threatening side effects such as slowed or stopped breathing, and dangerous changes in heart beat in patients receiving methadone. These serious side effects may occur because methadone may build up in the body to a toxic level if it is taken too often, if the amount taken is too high, or if it is taken with certain other medicines or supplements. Methadone has specific toxic effects on the heart (QT prolongation and Torsades de Pointes). Physicians prescribing methadone should be familiar with methadone's toxicities and unique pharmacologic properties. Methadone's elimination half-life (8-59 hours) is longer than its duration of analgesic action (4-8 hours). Methadone doses for pain should be carefully selected and slowly titrated to analgesic effect even in patients who are opioid-tolerant. Physicians should closely monitor patients when converting them from other opioids and changing the methadone dose, and thoroughly instruct patients how to take methadone. Healthcare professionals should tell patients to take no more methadone than has been prescribed without first talking to their physician.

*This information reflects FDA's current analysis of data available to FDA concerning this drug.
FDA intends to update this sheet when additional information or analyses become available*

Related Information

- [Information for Healthcare Professionals Methadone Hydrochloride text version 11/27/2006](#)
- [Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat 11/27/2006 Updated 7/2007](#)

- [Dolophine \(methadone\) label \(PDF - 136KB\)](#)
Approved on 11/17/2006

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