



Consumer Updates [11/2006]

Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat

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 has received reports of death and life-threatening side effects in patients taking methadone. These deaths and life-threatening side effects have occurred in patients newly starting methadone for pain control and in patients who have switched to methadone after being treated for pain with other strong narcotic pain relievers. Methadone can cause slow or shallow breathing and dangerous changes in heart beat that may not be felt by the patient.

Prescribing methadone is complex. Methadone should only be prescribed for patients with moderate to severe pain when their pain is not improved with other non-narcotic pain relievers. Pain relief from a dose of methadone lasts about 4 to 8 hours. However methadone stays in the body much longer—from 8 to 59 hours after it is taken. As a result, patients may feel the need for more pain relief before methadone is gone from the body. 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.

To prevent serious complications from methadone, health care professionals who prescribe methadone should read and carefully follow the methadone (Dolophine) prescribing information

FDA is issuing this public health advisory to alert patients and their caregivers and health care professionals to the following important safety information:

- **Patients should take methadone exactly as prescribed.** Taking more methadone than prescribed can cause breathing to slow or stop and can cause death. A patient who does not experience good pain relief with the prescribed dose of methadone, should talk to his or her doctor.
- **Patients taking methadone should not start or stop taking other medicines or dietary supplements without talking to their health care provider.** Taking other medicines or dietary supplements may cause less pain relief. They may also cause a toxic buildup of methadone in the body leading to dangerous changes in breathing or heart beat that may cause death.

- **Health care professionals and patients should be aware of the signs of methadone overdose.** Signs of methadone overdose include trouble breathing or shallow breathing; extreme tiredness or sleepiness; blurred vision; inability to think, talk or walk normally; and feeling faint, dizzy or confused. If these signs occur, patients should get medical attention right away.

FDA recently approved new prescribing information for methadone products approved for pain control. The information in the new prescribing information is based on a review of the scientific literature completed by FDA. A Medication Guide for patients is planned.