





## Information for Healthcare Professionals

### Methadone Hydrochloride

methadone when converting patients from other opioids to methadone. Particular vigilance is necessary during treatment initiation, during conversion from one opioid to another, and during dose adjustments.

**Methadone can cause serious cardiac conduction effects, including QT interval prolongation and Torsades de Pointes.**

**There are pharmacokinetic and pharmacodynamic drug interactions between methadone and many other drugs.** Drugs administered concomitantly with methadone should be evaluated for interaction potential.

**Methadone is secreted into human milk.**

#### What should physicians do?

- Read and follow the prescribing information for methadone.
- Carefully weigh methadone's risks with its potential benefits before prescribing methadone.
- Avoid prescribing methadone 40 mg dispersible tablets for pain. This product is only FDA-approved for detoxification and maintenance treatment of narcotic addiction.
- Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments.

#### What should healthcare professionals tell patients when prescribing methadone for pain?

- Pain relief from methadone does not last as long as methadone stays in your body. Therefore, do not to take more methadone than prescribed because methadone could build up in your body and cause death.
- Methadone can cause life-threatening changes in breathing (it may slow or stop).
- Methadone can cause life-threatening changes to the heart beat that may not be felt.
- Seek medical attention right away if you experience symptoms suggestive of an arrhythmia such as palpitations, dizziness, lightheadedness, or fainting or if you experience symptoms suggestive of a methadone overdose such as slow or shallow breathing; extreme tiredness or sleepiness; blurred vision; inability to think, talk or walk normally; and feeling faint, dizzy or confused.
- Directions you should follow if your pain is not controlled after taking the prescribed amount of methadone.
- Pain relief from methadone should last longer after you have taken it for awhile.



Report serious adverse events to FDA's MedWatch reporting system by completing a form on line at <http://www.fda.gov/medwatch/report.htm>, by faxing (1-800-FDA-0178), by mail using the postage-paid address form provided online (5600 Fishers Lane, Rockville, MD 20852-9787), or by telephone (1-800-FDA-1088).



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- Tell your doctor if you start or stop other medicines because other medicines can interact with methadone and possibly cause death or life threatening side effects, or result in less pain relief from methadone.
- Tell your doctor if you are breastfeeding because methadone is secreted into human milk. Babies can experience the same serious side effects from methadone as the mother.

#### Data and Background Information

There have been reports of serious adverse events such as death, respiratory depression, and serious cardiac arrhythmias in patients receiving methadone. Fatalities have been reported in patients who were switched from chronic, high-dose treatment with other opioids to methadone and in patients initiating treatment with methadone. These adverse events may have resulted from unintentional methadone overdoses, drug interactions, and/or methadone's cardiac toxicities (QT prolongation and Torsades de Pointes). Some of the unintentional overdoses were due to prescribers not being aware of methadone's pharmacokinetics and potential adverse effects.

FDA recently updated the methadone label following an extensive review of the medical literature and other available information. The new label provides new information on methadone's pharmacology, drug interactions, and instructions on converting patients from other opioids to methadone and dosing methadone based on a synthesis of recommendations from several palliative care organizations and treatment centers.

#### References

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- Pereira J, Lawlor P, Vigano A, Dorgan M, Bruera E. Equianalgesic dose ratios for opioids. a critical review and proposals for long-term dosing. *J Pain Symptom Manage*. 2001 Aug;22(2): 672-87.



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