

## **MEDICATION GUIDE**

### **METHADONE HYDROCHLORIDE**

**(meth' a done hye" droe klor' ide)**

**Oral Solution, CII**

#### **Methadone Hydrochloride Oral Solution USP is:**

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.
- Also used to manage drug addiction.

#### **Important information about Methadone Hydrochloride Oral Solution:**

- **Get emergency help or call 911 right away if you take too much Methadone Hydrochloride Oral Solution (overdose).** When you first start taking Methadone Hydrochloride Oral Solution, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking Methadone Hydrochloride Oral Solution with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your Methadone Hydrochloride Oral Solution. They could die from taking it. Selling or giving away Methadone Hydrochloride Oral Solution is against the law.
- Store Methadone Hydrochloride Oral Solution securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

#### **Do not take Methadone Hydrochloride Oral Solution if you have:**

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

#### **Before taking Methadone Hydrochloride Oral Solution, tell your healthcare provider if you have a history of:**

- head injury, seizures
- pancreas or gallbladder problems
- liver, kidney, thyroid problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems
- problems urinating
- heart rhythm problems (Long QT syndrome)

#### **Tell your healthcare provider if you are:**

- **pregnant or plan to become pregnant.** If you take Methadone Hydrochloride Oral Solution while pregnant, your baby may have symptoms of opioid withdrawal or respiratory depression at birth. Talk to your doctor if you are pregnant or plan to become pregnant.
- **breastfeeding.** Methadone Hydrochloride Oral Solution passes into breast milk and may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking Methadone Hydrochloride Oral Solution with certain other medicines may cause serious side effects.

#### **When taking Methadone Hydrochloride Oral Solution:**

- Do not change your dose. Take Methadone Hydrochloride Oral Solution exactly as prescribed by your healthcare provider.
- Always use a calibrated measuring device for Methadone Hydrochloride Oral Solution to correctly measure your dose. A household teaspoon or tablespoon is not an adequate measuring device. Given the inexactitude of the household spoon measure and the possibility of using a tablespoon instead of a teaspoon, which could lead to overdose,

it is strongly recommended that caregivers obtain and use a calibrated measuring device.

- Do not take more than your prescribed dose in 24 hours. If you take Methadone Hydrochloride Oral Solution for pain and miss a dose, take Methadone Hydrochloride Oral Solution as soon as possible and then take your next dose 8 or 12 hours later as directed by your healthcare provider. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- If you take Methadone Hydrochloride Oral Solution for opioid addiction and miss a dose, take your next dose the following day as scheduled. Do not take extra doses. Taking more than the prescribed dose may cause you to overdose because Methadone Hydrochloride Oral Solution builds up in your body over time.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking Methadone Hydrochloride Oral Solution without talking to your healthcare provider.**
- Dispose of expired, unwanted, or unused Methadone Hydrochloride Oral Solution by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**While taking Methadone Hydrochloride Oral Solution DO NOT:**

- Drive or operate heavy machinery, until you know how Methadone Hydrochloride Oral Solution affects you. Methadone can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with Methadone Hydrochloride Oral Solution may cause you to overdose and die.

**The possible side effects of Methadone Hydrochloride Oral Solution are:**

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

**Get emergency medical help or call 911 right away if you have:**

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of Methadone Hydrochloride Oral Solution. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov).**

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