Medication Guide

Methadone Hydrochloride Tablets USP, CII
(METH a done HYE droe KLOR ide)
Rx only

Methadone hydrochloride tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine, when other pain 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 than can lead to death.
- Not to be taken on an "as needed" basis.
- Also used to manage drug addiction.

Important information about methadone hydrochloride tablets:

- **Get emergency help or call 911 right away if you take too much methadone hydrochloride tablets (overdose).** When you first start taking methadone hydrochloride tablets, 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 emergency treatment of opioid overdose.
- Taking methadone hydrochloride tablets 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 tablets. They could die from taking it. Selling or giving away methadone hydrochloride tablets is against the law.
- Store methadone hydrochloride tablets 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 tablets 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 tablets, tell your healthcare provider if you have a history of:

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

Tell your healthcare provider if you are:

- noticing your pain getting worse. If your pain gets worse after you take methadone hydrochloride tablets, do not take more of methadone hydrochloride tablets without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking methadone hydrochloride tablets.
- **pregnant or plan to become pregnant.** If you take methadone hydrochloride tablets while pregnant, your baby may have symptoms of opioid withdrawal or respiratory depression at birth. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- **breastfeeding.** Methadone passes into breast milk and may harm your baby. Carefully observe infants for increased sleepiness (more than usual), breathing difficulties, or limpness. Seek immediate medical care if you notice these signs.
- 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 tablets with certain other medicines may cause serious side effects.

When taking methadone hydrochloride tablets:

- Do not change your dose. Take methadone hydrochloride tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Do not take more than your prescribed dose in 24 hours. If you take methadone hydrochloride tablets for pain and miss a dose, take methadone hydrochloride tablets 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 tablets 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 tablets build up in your body over time.
- Do not crush, dissolve, snort or inject methadone hydrochloride tablets because this may cause you to overdose and die.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking methadone hydrochloride tablets without talking to your healthcare provider.**
- Dispose of expired, unwanted, or unused methadone hydrochloride tablets by promptly flushing down the toilet, if a drug takeback option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking methadone hydrochloride tablets DO NOT:

- Drive or operate heavy machinery, until you know how methadone hydrochloride tablets affect you. Methadone hydrochloride tablets 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 tablets may cause you to overdose and die.

The possible side effects of methadone hydrochloride tablets 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, lightheadedness 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 tablets. Call your healthcare provider 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.**

For more information, please call 1-800-778-7898.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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