

Methadone

o Tablets: 5 mg, 10 mg

o Oral tablet for suspension: 40 mg

o Oral solution: 5 mg/5ml; 10 mg/5ml, 10 mg/ml, 5 mg/ 0.5ml

o Injection solution: 10 mg/ml

Diskets Dispersible[®]

o Tablets: 40 mg

Methadone Intensol[®]

o Oral solution: 10 mg/ml

Methadose[®]

o Tablets: 40 mg

o Oral tablet for suspension: 40 mg

o Oral solution: 10 mg/ml

If you or someone you know is in crisis, please call 911 and/or the toll-free National Suicide Prevention Lifeline at 800-273-TALK (8255) to speak with a trained crisis counselor 24/7. A help line and other resources are also



available through the National Alliance on Mental Illness at nami.org.

Medication Assisted Treatment (MAT)

Medication assisted treatment (MAT) is the use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders. A combination of medication and behavioral therapies is effective in the treatment of substance use disorders and can help some people to sustain recovery.

What is methadone and what does it treat?

Methadone is a prescription medication that works in the brain to treat pain and opioid use disorder. Opioids include heroin and prescription pain relievers such as hydrocodone, oxycodone, morphine, fentanyl, and methadone. Though methadone is in the same family as opioids, its long activity in the body makes it suitable for reducing cravings for other opioids and easier to taper a person off of these drugs. It is important to combine methadone treatment with counseling and other support.

Symptoms of opioid use disorder include:

- Being unable to quit using opioids despite problems with health and relationships
- Needing more opioids to achieve the same effect
- Going through withdrawal symptoms (sweating, shaking, nausea, vomiting, diarrhea, discomfort, anxiety) when unable to use opioids
- Spending the majority of time using or finding a way to use opioids
- Having a desire but an inability to decrease the amount of opioids used
- Giving up enjoyable activities in order to use opioids

What is the most important information I should know about methadone?

Your physician will usually transition you gradually between the opioid drug you are using to methadone. This detoxification process using methadone first starts in a controlled in-patient hospital setting, then transitions to a controlled clinic setting in conjunction with counseling at the same site. For opioid use disorder, methadone is highly regulated and cannot be prescribed or picked up at an outpatient pharmacy. You may be prescribed other medications with methadone to help reduce withdrawal side effects. Methadone is also used for the management of painful conditions that have been difficult to manage with other treatments. It may be available on an out-patient basis if prescribed by a pain doctor.

Do not stop taking methadone unless directed to by your physician. Your methadone will need to be taken exactly as directed by your physician.



Do not stop taking methadone, even when you feel better. Only your health care provider can determine the length of treatment that is right for you. If methadone is stopped abruptly, you may have withdrawal symptoms such as sweating, shaking, nausea, vomiting, diarrhea, body aches, anxiety, irritability, or runny nose.

Missing doses of methadone may increase your risk for relapse.

Respiratory depression (slowed breathing) and death can rarely happen when methadone is taken as prescribed. This risk is increased when methadone is injected into the body or when it is mixed with other depressants including benzodiazepine medications and alcohol.

Do not crush, chew, dissolve, snort or inject ("shoot-up") methadone tablets. This can cause uncomfortable symptoms including respiratory depression (slowed breathing) or death.

Methadone is sometimes used as a pain reliever. There have been deaths reported in people who have never used opioids before after using methadone.

Methadone is not recommended in people with severe liver disease. Liver injury is rare and this can be monitored through blood tests. Alert your doctor immediately if you experience any yellowing of your skin and/or eyes, severe stomach pain, or severe nausea or vomiting.

Tell all of your providers and pharmacists that you are on methadone. You should not take other medications with methadone without talking to your provider.

Do not drive or operate heavy machinery until you know how you will respond to methadone.

Store methadone out of the reach of children. Methadone can cause serious respiratory depression (slowed breathing) and death in children.

Avoid alcohol while taking this medication.

If you are taking this opioid medication with other medications called benzodiazepines (alprazolam, clonazepam, lorazepam, etc.) or other sedating medications, get medical assistance immediately if you feel dizziness or sleepiness, if you have slow or troubled breathing, or if you pass out. Caregivers must get medical help right away if a patient does not respond and does not wake up.

Patients with opioid use disorders are at high risk for depression and suicidal thoughts. If you experience any increased thoughts of suicide, call 911 or go to your closest emergency room.

Are there specific concerns about methadone and pregnancy?

If you are planning on becoming pregnant, notify your health care provider to best manage your medications. People living with substance use disorders that wish to become pregnant face important decisions and challenges. Active substance use disorders during pregnancy put the fetus at great risk. It is important to discuss the risks and benefits of continued treatment with your doctor and caregivers.

Opioid use disorder in pregnancy is associated with adverse outcomes such as low birth weight, preterm birth, and fetal death. Receiving treatment for opioid use disorder during pregnancy lower these risks.

Methadone crosses the placenta and can be detected in cord blood, amniotic fluid, and newborn urine.

Methadone and buprenorphine are considered the standards of care when treating opioid use disorder in pregnant women. Methadone may be removed from the body faster during pregnancy, so pregnant women may need increased doses of methadone. This is something only your health care provider can determine. Women receiving methadone for the treatment of opioid use disorder should be maintained on their daily dose of methadone in addition to receiving the same pain management options during labor and delivery as women who are not receiving treatment for opioid use disorder.

Pregnant women in methadone treatment programs are reported to have improved fetal outcomes compared to pregnant women using illegal drugs. A baby's growth in the uterus, birth weight, length, and/or head circumference may be decreased in infants born to mothers treated with methadone during pregnancy. Growth deficits do not appear to last; however, decreased performance on behavioral tests have been found to continue into childhood.



There was evidence of obstructed labor, fetal death, neonatal death, and developmental delays in animal studies. Opioid withdrawal symptoms may occur in newborn infants of women who were taking methadone during pregnancy. There have been reports of irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, sneezing, yawning, vomiting, diarrhea, and fever.

Methadone is excreted into breast milk; the dose to a nursing infant has been calculated to be 2% to 3% of the mother's dose. Peak methadone levels appear in breast milk 4 to 5 hours after an oral dose. Sedation and slowed breathing have been reported in nursing infants. Your physician may recommend that you monitor your nursing infant for sedation and you should be instructed as to when to contact them for emergency care.

If you are nursing, and methadone is used to treat opioid use disorder, breastfeeding is likely to be safe as long as your baby is tolerating the effects. Your physician will decide when it is appropriate for you to breastfeed.

What should I discuss with my health care provider before taking methadone?

- Symptoms of your condition that bother you the most
- If you have allergies to any medications
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you experience side effects from your medications. Some side effects may pass with time, but others may require changes in the medication.
- Any other psychiatric or medical problems you have, including a history of liver disease
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements)
- Other non-medication treatments you are receiving, such as talk therapy or counseling. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you use illegal drugs or narcotics

How should I take methadone?

Methadone is available as an oral tablet or liquid. Methadone tablets should not be crushed, chewed, or snorted because of the risk of overdose and death. You should not take an extra dose of methadone just because it feels like it's not working. A single dose of 20 to 30 mg is usually used to decrease withdrawal symptoms. Lower doses should be considered in patients with low tolerance at initiation. An additional 5 to 10 mg of methadone may be provided if withdrawal symptoms have not been decreased or if symptoms reappear after 2 to 4 hours; total daily dose on the first day should not exceed 40 mg. Your doctor will decide when and whether to change your dose based on the symptoms you are experiencing.

Your doctor will adjust your dosage to one which prevents withdrawal symptoms for 24 hours.

What happens if I miss a dose of methadone?

If you miss a dose of methadone, take it as soon as you remember unless it is closer to the time of your next dose. Do not double your next dose or take more than what is prescribed.

What should I avoid while taking methadone?

Avoid drinking alcohol, using sedatives, or other opioid pain medications (such as codeine, hydrocodone, oxycodone, or morphine), or using illegal drugs while you are taking methadone. They may increase adverse effects (e.g., sedation, overdose, death) of the medication.

Keep in mind that some cough syrups may contain opioid pain medication. Discuss all medications with your doctor and pharmacist prior to taking methadone.

What happens if I overdose with methadone?

If an overdose occurs, call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.



Naloxone injection or nasal spray can be used to reverse an overdose from opioids including methadone. You should always call 911 after giving someone naloxone to treat an overdose. Ask your provider if prescription naloxone is right for you or your family member to have available.

What are the possible side effects of methadone?

Common side effects

- Headache, nausea, vomiting, lightheadedness, dizziness, sedation, increased sweating, constipation, and swelling in the arms and legs (peripheral edema)
- Signs and symptoms of withdrawal from opioids (such as shaking, stomach cramps, diarrhea, restlessness, irritability, anxiety, insomnia, body aches, or runny nose)

Rare/serious side effects

- · Orthostatic hypotension (low blood pressure when standing)
- Irregular heart rhythms
- Changes in liver function or liver failure
- Allergic reactions
- Overdose and death
 - o Signs of overdose include pinpoint pupils, sedation, low blood pressure, and respiratory depression (slowed breathing)
 - This risk is higher when methadone is injected or use at the same time with sedatives (like benzodiazepines) or other depressants (like alcohol)

Are there any risks for taking methadone for long periods of time?

Methadone causes physical dependency when taken daily for a long period of time. This means that you may have withdrawal symptoms if methadone is stopped abruptly. Talk to your provider before stopping methadone.

What other medications may interact with methadone?

There have been reports of respiratory depression (slowed breathing) and death in patients taking methadone with benzodiazepine medications such as alprazolam (Xanax®), clonazepam (Klonopin®), diazepam (Valium®), lorazepam (Ativan®), and temazepam (Restoril®). These medications should be taken exactly as prescribed. It is very dangerous to take methadone with benzodiazepines if you do not have a prescription.

Using methadone with antipsychotics, , antibiotics, tricyclic antidepressants, and certain heart medications may increase the risk of developing irregular heart rhythms

The following medications may increase the effects of methadone:

- Certain antibiotics such as clarithromycin (Biaxin®) and erythromycin (Ery-Tab®)
- Certain antidepressants such as fluoxetine (Prozac®), and paroxetine (Paxil®)
- Antifungals, such as fluconazole (Diflucan®), ketoconazole (Nizoral®), and itraconazole (Sporanox®)
- Heart medications such as amiodarone

The following medications may decrease the effects of methadone:

- The opioid "blocker" naltrexone (Revia[®], Vivitrol[®])
- Certain antiviral medications known such as telaprevir (IncivekTM), ritonavir (Norvir®), saquinavir (Fortovase®, Invirase®), and lopinavir/ritonavir (Kaletra®)
- Certain seizure medications such as phenobarbital, carbamazepine (Tegretol®), and phenytoin (Dilantin®)
- The antibiotic rifampin (Rifadin®)

Your pharmacist or doctor will help you to determine if other medications you take can interfere with the effects of methadone.

How long does it take for methadone to work?

Methadone will begin working shortly after taking one dose, but you may not feel the full effect of the initial dose for 4 or more days.



Summary of Black Box Warnings

Patients taking methadone may develop heart-related effects that can lead to irregular heartbeats, which can cause sudden death. Your doctor will want to ask you questions about heart disease and monitor your heart regularly during treatment.

Methadone may cause serious, life-threatening, or fatal decrease in breathing. Your doctor may monitor you closely for breathing, especially when beginning treatment with methadone or when increasing your dose.

Methadone is an opiate and a Schedule II controlled substance with risks of opioid misuse which can lead to overdose and death. The FDA has found that the use of opiate drugs with benzodiazepine drugs or other sedating medications can result in serious adverse reactions including slowed or difficult breathing and death. Benzodiazepine drugs include drugs like alprazolam, clonazepam, and lorazepam. Benzodiazepine drugs are used to treat health problems like anxiety, trouble sleeping, or seizures. Patients taking opioids with benzodiazepines, other sedating medications, or alcohol, and caregivers of these patients, should seek immediate medical attention if they start to experience unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficulty breathing, or unresponsiveness.

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.