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## Methadone

pronounced as (meth' a done)

### IMPORTANT WARNING:

Methadone may cause serious or life-threatening breathing problems, especially during the first 72 hours of your treatment and any time your dose is increased. Your doctor will monitor you carefully during your treatment. Tell your doctor if you have or have ever had slowed breathing or asthma. Your doctor will probably tell you not to take methadone. Also tell your doctor if you have or have ever had lung disease such as chronic obstructive pulmonary disease (COPD; a group of lung diseases that includes chronic bronchitis and emphysema), a head injury, or any condition that increases the amount of pressure in your brain. The risk that you will develop breathing problems may be higher if you are an older adult or are weak or malnourished due to disease. If you experience any of the following symptoms, call your doctor immediately or get emergency medical treatment: slowed breathing, long pauses between breaths, or shortness of breath.

Taking certain other medications during your treatment with methadone may increase the risk that you will experience serious, life-threatening side effects. Tell your doctor if you are taking or plan to take any of the following medications: antidepressants, other narcotic pain medications; medications for anxiety, nausea, or mental illness; muscle relaxants; sedatives; sleeping pills; or tranquilizers. Your doctor may need to change the doses of your medications and will monitor you carefully.

Drinking alcohol, taking prescription or non-prescription medications that contain alcohol, using street drugs, or overusing prescription medications such as benzodiazepines during your treatment with methadone increases the risk that you will experience serious, life-threatening side effects. Talk to your doctor about the risks of drinking alcohol or using street drugs during your treatment.

Methadone may be habit-forming. Do not take a larger dose, take it more often, or take it for a longer period of time or in a different way than prescribed by your doctor. Tell your

doctor if you or anyone in your family drinks or has ever drunk large amounts of alcohol, uses or has ever used street drugs, or has overused prescription medications, or if you have or have ever had depression or another mental illness. There is a greater risk that you will overuse methadone if you have or have ever had any of these conditions.

Do not allow anyone else to take your medication. Methadone may harm or cause death to other people who take your medication, especially children. Store methadone in a safe place so that no one else can take it accidentally or on purpose. Be especially careful to keep methadone out of the reach of children. Keep track of how many tablets or how much liquid is left so you will know if any medication is missing. Dispose of any unwanted methadone tablets or oral solution properly according to instructions. (See STORAGE and DISPOSAL.)

Methadone may cause a prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death). Tell your doctor if you or anyone in your family has or has ever had long QT syndrome; or if you have or ever had a slow or irregular heartbeat; low blood levels of potassium or magnesium, or heart disease. Tell your doctor and pharmacist if you are taking or plan to take any of the following medications: antidepressants such as amitriptyline, amoxapine, clomipramine (Anafranil), desipramine (Norpramin), doxepin (Silenor), imipramine (Tofranil), nortriptyline (Aventyl, Pamelor), protriptyline (Vivactil), and trimipramine (Surmontil); certain antifungals such as fluconazole (Diflucan), itraconazole (Onmel, Sporanox), ketoconazole (Nizoral), and voriconazole (Vfend); diuretics ('water pills'); erythromycin (Eryc, Erythrocin); fludrocortisone; certain laxatives; medications for irregular heartbeat such as amiodarone (Cordarone, Pacerone, Nexterone), disopyramide (Norpace), dofetilide (Tikosyn), ibutilide (Corvert), flecainide, procainamide, and quinidine (Quinidex, in Nuedexta); nicardipine (Cardene); risperidone (Risperdal); and sertraline (Zoloft). If you experience any of the following symptoms, call your doctor immediately: pounding heartbeat, dizziness, lightheadedness, or fainting.

Tell your doctor if you are pregnant or plan to become pregnant. If you take methadone regularly during your pregnancy, your baby may experience life-threatening withdrawal symptoms after birth. Tell your baby's doctor right away if your baby experiences any of the following symptoms: irritability, hyperactivity, abnormal sleep, high-pitched cry, uncontrollable shaking of a part of the body, vomiting, diarrhea, or failure to gain weight.

Talk to your doctor about the risks of taking methadone for your condition.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with methadone and each time you fill your prescription if a Medication Guide is available for the methadone product you are taking. Read the information carefully and ask your doctor or pharmacist if you have any

questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

Use of methadone to treat opiate addiction:

If you have been addicted to an opiate (narcotic drug such as heroin), and you are taking methadone to help you stop taking or continue not taking the drug, you must enroll in a treatment program. The treatment program must be approved by the state and federal governments and must treat patients according to specific federal laws. You may have to take your medication at the treatment program facility under the supervision of the program staff. Ask your doctor or the treatment program staff if you have any questions about enrolling in the program or taking or getting your medication.

## Why is this medication prescribed?

Methadone is used to relieve severe pain in people who are expected to need pain medication around the clock for a long time and who cannot be treated with other medications. It also is used to prevent withdrawal symptoms in patients who were addicted to opiate drugs and are enrolled in treatment programs in order to stop taking or continue not taking the drugs. Methadone is in a class of medications called opiate (narcotic) analgesics. Methadone works to treat pain by changing the way the brain and nervous system respond to pain. It works to treat people who were addicted to opiate drugs by producing similar effects and preventing withdrawal symptoms in people who have stopped using these drugs.

## How should this medicine be used?

Methadone comes as a tablet, a dispersible (can be dissolved in liquid) tablet, a solution (liquid), and a concentrated solution to take by mouth. When methadone is used to relieve pain, it may be taken every 8 to 12 hours. If you take methadone as part of a treatment program, your doctor will prescribe the dosing schedule that is best for you. Follow the directions on your prescription label carefully and ask your doctor or pharmacist to explain any part you do not understand. Take methadone exactly as directed.

If you are using the dispersible tablets, do not chew or swallow before mixing the tablet in a liquid. If your doctor has told you to take only part of a tablet, break the tablet carefully along the lines that have been scored into it. Place the tablet or piece of the tablet in at least 120 mL (4 ounces) of water, orange juice, Tang®, citrus flavors of Kool-Aid®, or a citrus fruit drink to dissolve. Drink the entire mixture right away. If some tablet residue remains in the cup after you drink the mixture, add a small amount of liquid to the cup and drink it all.

Your doctor may change your dose of methadone during your treatment. Your doctor may decrease your dose or tell you to take methadone less often as your treatment continues. If you experience pain during your treatment, your doctor may increase your dose or may prescribe an additional medication to control your pain. Talk to your doctor about how you are feeling during your treatment with methadone. Do not take extra doses of methadone or take doses of methadone earlier than they are scheduled even if you experience pain.

Do not stop taking methadone without talking to your doctor. Your doctor will probably want to decrease your dose gradually. If you suddenly stop taking methadone, you may experience withdrawal symptoms such as restlessness, teary eyes, runny nose, yawning, sweating, chills, muscle pain, widened pupils (black circles in the middle of the eyes), irritability, anxiety, backache, joint pain, weakness, stomach cramps, difficulty falling asleep or staying asleep, nausea, decreased appetite, vomiting, or diarrhea.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking methadone,

- tell your doctor and pharmacist if you are allergic to methadone, any other medications, or any of the ingredients in the methadone product you plan to take. Ask your doctor or pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: antihistamines; buprenorphine (Suboxone, in Zubsolv); butorphanol; calcium channel blocking agents such as carbamazepine (Cabatrol, Equetro, Tegretol); fluvoxamine (Luvox); certain medications for HIV including abacavir (Ziagen, in Trizivir), darunavir (Prezista), didanosine (Videx), efavirenz (Sustiva, in Atripla), lopinavir (in Kaletra), nelfinavir (Viracept), nevirapine (Viramune), ritonavir (Norvir, in Kaletra), saquinavir (Invirase), stavudine (Zerit), telaprevir (Incivek), tipranavir (Aptivus), and zidovudine (Retrovir, in Combivir); medications for glaucoma, irritable bowel disease, Parkinson's disease, ulcers, and urinary problems; nalbuphine; naloxone (in Zubsolv); naltrexone (ReVia, Depade); pentazocine (Talwin); phenobarbital; phenytoin (Dilantin); and rifampin (Rifadin, Rimactane, in Rifamate, in Rifater). Also tell your doctor or pharmacist if you are taking the following medications or have stopped taking them in the past 14 days: monoamine oxidase (MAO) inhibitors including isocarboxazid (Marplan), phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelpar), and tranylcypromine (Parnate). Many other medications may also interact with methadone, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have any of the conditions mentioned in the IMPORTANT WARNING section or have or have ever had paralytic ileus (condition in which digested food does not move through the intestines). Your doctor may tell you that you should not take methadone.
- tell your doctor if you have or have ever had a blockage in your intestine; difficulty urinating; an enlarged prostate (a male reproductive gland); Addison's disease (a condition in which the adrenal gland does not make enough of certain natural substances); seizures; or thyroid, pancreas, gallbladder, liver, or kidney disease.
- tell your doctor if you are breast-feeding. If you breast-feed during your treatment with methadone, your baby may receive some methadone in breastmilk. Watch your baby closely for any changes in behavior or breathing, especially when you start taking methadone. If your baby develops any of these symptoms, call your baby's doctor immediately or get emergency medical help: unusual sleepiness, difficulty breastfeeding, difficulty breathing, or limpness. Talk to your baby's doctor when you are ready to wean your baby. You will need to wean your baby gradually so that your baby will not develop withdrawal symptoms when he or she stops receiving methadone in breastmilk.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking methadone.
- you should know that this medication may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that methadone may cause dizziness when you get up too quickly from a lying position. This is more common when you first start taking methadone. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that methadone may cause constipation. Talk to your doctor about changing your diet or using other medications to prevent or treat constipation while you are taking methadone.

## What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

## What should I do if I forget a dose?

If your doctor has told you to take methadone for pain, take the missed dose as soon as you remember it and then continue your regular dosing schedule. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If you are taking methadone to treat opioid addiction, skip the missed dose and take the next

dose the next day as scheduled. Do not take a double dose to make up for a missed one.

## **What side effects can this medication cause?**

**Methadone may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- weakness
- headache
- nausea
- vomiting
- loss of appetite
- weight gain
- stomach pain
- dry mouth
- sore tongue
- sweating
- flushing
- difficulty urinating
- mood changes
- vision problems
- difficulty falling asleep or staying asleep
- decreased sexual desire or ability
- missed menstrual periods

**Some side effects can be serious. If you experience any of the following symptoms or those mentioned in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical help:**

- seizures
- itching
- hives
- rash
- swelling of the eyes, face, mouth, tongue, or throat
- hoarseness

- difficulty breathing or swallowing
- extreme drowsiness
- hallucinating (seeing things or hearing voices that do not exist)

Methadone may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

## **What should I know about storage and disposal of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Flush any methadone tablets or solution that is outdated or no longer needed down the toilet. Talk to your pharmacist about the proper disposal of your medication.

## **In case of emergency/overdose**

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

## **Symptoms of overdose may include:**

- small, pinpoint pupils (black circles in the center of the eyes)
- slow or shallow breathing
- drowsiness
- cool, clammy, or blue skin
- loss of consciousness (coma)
- limp muscles

## **What other information should I know?**

Keep all appointments with your doctor or clinic. Your doctor will want to check your response to methadone.

This prescription is not refillable. If you continue to experience pain after you finish taking the methadone, call your doctor. If you take this medication on a regular basis, be sure to schedule appointments with your doctor so that you do not run out of medication.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you

in case of emergencies.

## Brand names

- Diskets ®
- Dolophine ®
  
- Methadose ®
- Methadose ® Oral Concentrate
  
- Westadone ® ¶

¶ – This branded product is no longer on the market. Generic alternatives may be available.

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