Methadone dispersible tablets for oral suspension

MEDICATION GUIDE

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

What is this medicine?
METHADONE (METH a done) is a pain reliever. It is used to treat severe pain. The medicine is also used to prevent withdrawal symptoms in people addicted to other drugs.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?
Take the medicine by mouth. Determine the number of tablets you need for your dose. Dissolve the tablets in a glass of water, orange juice, citrus Tang, or citrus flavors of Kool-Aid. Stir well for one minute. You will see some of the tablet in the glass. The tablet will not completely melt. Drink all of the liquid in the glass. Do not chew or swallow whole tablets. The tablets must be dissolved. If the medicine upsets your stomach, take the medicine with food or milk. Follow the directions on the prescription label. Do not take more medicine than you are told to take.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?
If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?
They need to know if you have any of these conditions:

- Adrenal gland problem (Addison’s disease)
- Brain tumor
- Drug abuse or addiction
- Fast or irregular heartbeat
- Gallbladder disease
- Head injury
- Frequently drink alcohol-containing drinks
- Kidney disease or problems going to the bathroom
- Liver disease
- Low blood pressure
- Lung disease, asthma, COPD, or sleep apnea
- Mental problems
- Seizure disorder
- Thyroid disease
- An unusual or allergic reaction to methadone, other opioid analgesics, other medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

What may interact with this medicine?
Do not take this medicine with any of the following medications:

- Antibiotics like chloroquine, clarithromycin, erythromycin, grepafloxacin, pentamidine, sparfloxacin, troleandomycin
- Arsenic trioxide
- Cisapride
- Droperidol
- Halofantrine
- Haloperidol
- Medicines for irregular heart beat like amiodarone, bretylium, disopyramide, dofetilide, procainamide, quinidine, sotalol
- Pimozide
- Ranolazine
- Rasagiline
This medicine may also interact with the following medications:

- Alcohol
- Alfuzosin
- Antibiotics like gatifloxacin, gemifloxacin, levofloxacin, mefloquine, moxifloxacin, ofloxacin, telithromycin
- Antihistamines for allergy, cough and cold
- Desipramine
- MAOIs like Carbex, Eldepryl, Marplan, Nardil, and Parnate
- Medicines for blood pressure
- Medicines for depression, anxiety, or psychotic disturbances
- Medicines for irregular heart beat like flecainide, propafenone
- Medicines for nausea or vomiting like dolasetron, ondansetron, palonosetron
- Medicines for seizures like carbamazepine, phenobarbital, phenytoin
- Medicines for sleep
- Medicines for sleep during surgery
- Medicines to numb the skin
- Muscle relaxants
- Narcotic medicines (opiates) for pain
- Octreotide
- Peginterferon Alfa-2b
- Phenothiazines like chlorpromazine, mesoridazine, prochlorperazine, thioridazine
- Rifampin, rifapentine
- Some medicines for cancer like dasatinib, lapatinib, sunitinib
- Some medicines for HIV like delavirdine, didanosine, efavirenz, nevirapine
- St. John’s wort
- Tacrolimus
- Tramadol
- Vardenafil
- Vorinostat

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:

- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- Breathing problems
- Chest pain
- Confusion
- Feeling faint or lightheaded, falls
- Hallucinations
- Loud snoring
- Unusually fast, pounding, or slow heartbeat
- Unusually weak or tired

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):

- Nausea, vomiting
- Sweating

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Tell your doctor or health care professional if your pain does not go away, if it gets worse, or if you have new or a different type of pain. You may develop tolerance to the medicine. Tolerance means that you will need a higher dose of the medicine for pain relief. Tolerance is normal and is expected if you take this medicine for a long time.

Talk to your family and any people you live with about the side effects of this medicine. Tell them to get medical help if you have trouble breathing, unusually loud snoring, or are too sleepy.

Do not suddenly stop taking your medicine because you may develop a severe reaction. Your body becomes used to the medicine. This does NOT mean you are addicted. Addiction is a behavior related to getting and using a drug for a non-medical reason. If you have pain, you have a medical reason to take pain medicine. Your doctor will tell you how much medicine to take. If your doctor wants you to stop the medicine, the dose will be slowly lowered over time to avoid any side effects.

You may get drowsy or dizzy when you first start taking this medicine or change doses. Do not drive, use machinery, or do anything that may be dangerous until you know how the medicine affects you. Stand or sit up slowly.
There are different types of narcotic medicines (opiates) for pain. If you take more than one type at the same time, you may have more side effects. Give your health care provider a list of all medicines you use. Your doctor will tell you how much medicine to take. Do not take more medicine than directed. Call emergency for help if you have problems breathing.

This medicine will cause constipation. Try to have a bowel movement at least every 2 to 3 days. If you do not have a bowel movement for 3 days, call your doctor or health care professional.

Your mouth may get dry. Chewing sugarless gum or sucking hard candy, and drinking plenty of water may help. Contact your doctor if the problem does not go away or is severe.

Women should inform their doctor if they wish to become pregnant or think they might be pregnant. There is a potential for serious side effects to an unborn child. Talk to your doctor about the benefits and risks of breastfeeding while using this medicine. This medicine does pass into breast milk. Talk to your doctor if you plan to begin or stop using this medicine while breastfeeding or if you plan to stop breastfeeding.

Where should I keep my medicine?

Keep out of the reach of children. This medicine can be abused. Keep your medicine in a safe place to protect it from theft. Do not share this medicine with anyone. Selling or giving away this medicine is dangerous and is against the law.

Store at room temperature between 20 and 25 degrees C (68 and 77 degrees F). Keep container tightly closed.

Discard unused medicine and used packaging carefully. Pets and children can be harmed if they find used or lost packages. Flush any unused medicines down the toilet. Do not use the medicine after the expiration date.

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