

PACKAGE LEAFLET: INFORMATION FOR THE USER

Methadone 1mg/1ml Oral Solution sugar-free

Methadone Hydrochloride

(This medicine will be referred to as Methadone oral solution in this leaflet)

Read all of this leaflet carefully before you start taking Methadone oral solution because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Methadone oral solution is and what it is used for
2. What you need to know before you take Methadone oral solution
3. How to take Methadone oral solution
4. Possible side effects
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This medicine contains methadone, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

1. What Methadone oral solution is and what it is used for

This medicine has been prescribed for you for the treatment of addiction in order to reduce withdrawal symptoms. It contains the methadone which belongs to a class of medicines called opioids.

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Methadone oral solution

Do not take Methadone oral solution if:

- You are allergic to methadone or any of the ingredients of this medicine (listed in section 6).
- You have any problem with your breathing, any chronic lung disease or have an asthma attack.
- You are addicted to alcohol.
- You have a head injury and the pressure inside your brain is higher than it should be (check this with your doctor). You might be getting bad headaches.
- You are taking, or have recently stopped taking, a type of medicine called Monoamine Oxidase Inhibitors (MAOIs), including moclobemide which are used to treat depression, within the past two weeks.
- You are in labour.
- You have a bowel problem called ulcerative colitis.
- You are dependent on other non-opioid drugs.
- You have severe liver disease.
- You suffer from sudden involuntary muscle contraction of the bile ducts and kidney.

Methadone oral solution is not suitable for children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Methadone Oral Solution if:

- You are extremely ill or an older person. You may be more sensitive to the medicine.
- You have history of asthma or breathing difficulties.
- You have bowel problems.
- You have liver or kidney problems.
- You have a history of convulsions, fits or epilepsy.

- You have a history of low blood pressure.
- You have a history of under-active thyroid gland, or problems with your adrenal glands.
- You have a history of enlarged prostate gland.
- You have a condition that causes severe muscle weakness and fatigue (myasthenia gravis).
- You are in shock.
- You are taking medicines called CNS depressants to treat anxiety, acute stress and panic attacks.

If any of the conditions above apply to you, please consult your doctor.

Methadone may affect the electrical signals which control your heart contractions, particularly at high doses.

Tell your doctor you have recognised risk factors for the heart condition 'QT prolongation' that include if:

- you have a history of heart problems
- you have liver disease
- you have any blood abnormalities such as low levels of potassium or magnesium
- you have a history of sudden death in the family.

Taking this medicine regularly, particularly for a long time, can lead to addiction

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Long-term use may cause decreased sex hormone levels and increased levels of the hormone prolactin. Contact your doctor if you experience symptoms such as decreased libido, impotence or absence of menstruation (amenorrhoea).

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Methadone Oral Solution:

- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement.

During treatment, this medicine should not be stopped suddenly, but gradually, as sudden stoppage could lead to withdrawal symptoms.

Children and adolescents

Methadone Oral Solution is not suitable for children.

Other medicines and Methadone Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- medicines used to treat addiction e.g. naltrexone and buprenorphine.
- Cimetidine (a medicine used to treat stomach ulcers).
- medicines used to treat epilepsy such as phenytoin, carbamazepine, phenobarbital and primidone.
- naloxone (a medicine used to treat an overdose of opioid medicines).
- antibiotics (medicines used to treat bacterial infections) e.g. ciprofloxacin.
- antifungals (medicines used to treat fungal infections).
- medicines that make urine more acidic e.g. ammonium chloride.
- antiviral medicines including some medicines used to treat HIV e.g. nevirapine, zidovudine, efavirenz, nelfinavir and ritonavir.

- Medicines used to treat depression including fluvoxamine and fluoxetine, tricyclic antidepressants such as amitriptyline and imipramine, or MAOIs including moclobemide, must not be taken at the same time or within 2 weeks of taking MAOIs.
- CNS depressants (medicines that act on the brain and cause drowsiness or sleepiness).
- Pentazocine (a pain killer).
- Medicines used to help you relax (tranquillisers)
- Medicines used to help you to sleep (sedatives).
- Herbal medicines including St John's Wort.
- medicines used to treat tuberculosis (rifampicin).

The risk of side effects increases, if you use methadone concomitantly with antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, amitriptyline, clomipramine, imipramine, nortriptyline). Contact your doctor if you experience symptoms such as:

- mental-status changes (e.g. agitation, hallucinations, coma)
- fast heartbeat, unstable blood pressure, fever
- exaggeration of reflexes, impaired coordination, muscle stiffness
- gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea)

Other medicines you may be taking can also affect the heart. You must tell your doctor about any other medicines that you are taking as they may be dangerous if they are taken with methadone. In these situations your doctor may decide that it is necessary to monitor your heart with an electrocardiogram (ECG) at the start of treatment to ensure that these effects do not occur.

Concomitant use of Methadone oral solution and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Methadone oral solution together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Methadone oral solution with food and drink

You must not drink alcohol whilst you are taking Methadone oral solution as this could cause serious side effects.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast feeding, think you maybe pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

Talk to your doctor if you are breastfeeding or thinking of breast-feeding while you are taking methadone as it may affect your baby. Monitor your baby for abnormal signs and symptoms such as increased drowsiness (more than usual), breathing difficulties or limpness. Consult your doctor immediately if you notice any of these symptoms.

Pregnancy

Do not take Methadone Oral Solution if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Methadone Oral Solution during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding:

Do not take Methadone Oral Solution while you are breastfeeding as methadone passes into breast milk and will affect your baby.

Labour:

You should not take this medicine whilst you are in labour.

Driving and using machines

The ability to drive or use machinery may be severely affected during and after treatment with methadone. You must not drive or use machinery until you are told that you can do so by your doctor.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it

affects you.

- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Important information about some of the ingredients

Methadone oral solution contains:

- Colouring agent E110 (sunset yellow) which may cause an allergic reaction.
- liquid maltitol - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Methadone oral solution

You must only take Methadone oral solution by mouth. Under no circumstances should you inject this product as injection may cause serious and permanent damage to your body with possibly fatal consequences.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important that you do not take more than the dose agreed with your doctor. You can become dependent on Methadone oral solution.

Your prescriber should discuss your treatment and whether you need to continue taking Methadone Oral Solution at regular intervals. If you and your prescriber decide to stop treatment a plan will be put in place to gradually reduce the dose and stop taking the medicine to minimise the risk of withdrawal effects.

Adults:

The recommended initial dose is 10-20mg a day. The dose will be slowly increased until you show no signs of withdrawal or intoxication. The usual dose is 40-60mg per day.

Elderly or ill:

If you are elderly or ill, your doctor will only prescribe repeated doses with caution.

Use in children:

Not recommended. There is a serious risk of poisoning. Remember to keep your medicine safely where children can not get it.

If you forget to take Methadone oral solution

During a course of treatment it is important that, should you miss a dose, you take the dose as soon as you remember. However, if it is almost time for you to take your next dose, miss the dose and wait until the next scheduled dose.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.

If you stop taking Methadone Oral Solution

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you take more Methadone oral solution than you should

If you take too much Methadone oral solution, you can experience the following:

- difficulty in breathing
- extreme sleepiness, fainting or coma
- pin point pupils
- muscle weakness
- cold and clammy skin
- slow heartbeat, low blood pressure, heart attack or shock. In severe cases death may occur.

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- low blood sugar

In the event of overdose you should seek medical assistance immediately even if you feel well as you may be suffering methadone poisoning.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and see a doctor straight away if you have any of the following:

- heart problems. The signs of this may include changes in the way your heart beats, such as it beating faster or missed heart beats, breathing difficulties and dizziness
- if your breathing become slow and shallow.

Keep taking the medicine but tell your doctor straight away if you get any of the following side effects:

- if you have asthma and it gets worse
- worsening of the pressure inside your head if you already have this condition following an injury to your brain or brain disease.

Other side effects:

- feeling sick (nausea) or being sick (vomiting)
- constipation
- sweating a lot more than usual
- feeling dizzy, particularly when standing up. This may be a sign that you have low blood pressure
- small pupils
- breast growth and production of breast milk
- difficulty in passing water (urine), pain in the lower back and abdomen caused by muscle spasms
- dry mouth, eyes or nose, facial flushing
- feeling drowsy, confused or restless
- changes in your mood, feeling "high" or over excited
- seeing or hearing things that are not there (hallucinations)
- headache, rashes
- low body heat (hypothermia)
- painful periods or lack of periods
- high prolactin level in the blood
- dependence and addiction
- low blood sugar

Drug Withdrawal

When you stop taking Methadone Oral Solution, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

You may notice that some of the side effects become less severe with time as you get used to the methadone.

When taken for a long period of time, it is possible that you may become dependent on Methadone Oral Solution.

This product contains sunset yellow which may cause allergic reaction.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Methadone oral solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle. The expiry date refers to the last date of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Once you have opened the bottle you are advised to dispose of it after 4 weeks.

Do not store above 25°C.

6. Contents of the pack and other information

What Methadone oral solution contains:

The **active ingredient** is Methadone Hydrochloride 1mg/1ml.

The **other ingredients** are Maltitol liquid, Hydrochloric acid, sodium benzoate (E211), purified water and colours E110 (sunset yellow FCF), E142 (green S) and quinoline yellow (E104).

What Methadone oral solution looks like and the contents of the pack:

Methadone oral solution is a bright green liquid, supplied in amber glass bottles, each containing 500, 100, 50 or 30ml of the solution, or it is supplied in HDPE plastic bottles, each containing 5L, 2.5L, 1L or 500ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Martindale Pharmaceuticals Ltd, T/A Martindale Pharma, Bampton Road, Harold Hill, Essex RM3 8UG, UK

Manufacturer:

Thornton & Ross Limited
Linthwaite Huddersfield
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United Kingdom

Product licence number: PL 00156/0321

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If this leaflet is difficult to see or read, please contact the marketing authorisation holder for help.

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