

PATIENT INFORMATION LEAFLET

Methadone 1mg/ml Oral Solution B.P. Sugar Free

(Methadone Hydrochloride 1mg/ml)

This medicine contains methadone, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

Read all this leaflet carefully before you start taking this medicine.

- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is the medicine and what does it do?

The name of your medicine is Methadone 1mg/ml Oral Solution B.P. Sugar Free. It is a solution to be swallowed and is intended for adult use only.

What is it for?

This medicine has been prescribed for you to prevent withdrawal symptoms following addiction to opioid drugs such as heroin. It is important that it is taken regularly to reduce the risk of withdrawal symptoms occurring. 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. Before you take the medicine

Do not take the medicine if you:

- Are also taking heroin and/or other illegal substances.
- Are dependent on any other non opioid drugs.
- Are allergic to any of the ingredients listed under 'further information'.
- Have shallow breathing or other breathing difficulties. Do not use during an asthma attack.
- Have taken antidepressants known as Monoamine Oxidase Inhibitors (MAOIs) including moclobemide within the past two weeks.
- Have or have recently had a head injury.
- Are at risk of a type of blocked bowel called paralytic ileus following abdominal surgery.
- Are addicted to alcohol.
- Are in labour.
- Are breast feeding.

Ask your doctor for advice if any of these apply to you.

Methadone is not suitable for children (see section 3).

Warnings and precautions

Talk to your doctor or pharmacist if you have any of the following:

- Heart disease or other heart problems such as angina.
- Liver disease, including Hepatitis C.
- Kidney disease.
- Problems with your thyroid gland.
- Enlargement of your prostate gland.
- Hormonal problems.
- A family history of sudden death.
- Low levels of potassium or magnesium in your blood.
- Asthma.
- Or if you are elderly, or extremely ill, as these people can react differently to this medicine.
- Epilepsy.
- Low blood pressure.
- Shock.
- Problems with your adrenal glands.
- Bowel problems.
- Muscle weakness problems called myasthenia gravis.
- 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.

Tolerance, dependence, and addiction

This medicine contains methadone which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Methadone 1mg/ml Oral Solution can also lead

to dependence, abuse, and addiction, which may result in life-threatening overdose.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Methadone 1mg/ml Oral Solution if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ('addiction').
 - You are a smoker.
 - You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.
- If you notice any of the following signs whilst taking Methadone 1mg/ml Oral Solution, it could be a sign that you have become dependent or addicted.
- You need to take the medicine for longer than advised by your doctor.
 - You need to take more than the recommended dose.
 - You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'.
 - You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
 - When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Methadone 1mg/ml Oral Solution).

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).

Sleep-related breathing disorders

Methadone 1mg/ml Oral Solution can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Methadone 1 mg/ml Oral Solution

Concomitant use of methadone 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 this medicine 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.

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)

Also talk to your doctor or pharmacist if you are already taking any of the following:

These medicines may have a different effect when taking Methadone.

- Alcohol on a regular basis, including binge drinking (See Section 3).
- Any drugs which affect the heart.
- Drugs which affect the salt levels in your body.
- Drugs for depression or low mood/mild anxiety.
- Medicine for mental illness.
- Painkillers (other than Methadone).
- Sleeping tablets/mixtures or any other tranquillisers.
- Naloxone or naltrexone for drug or alcohol addiction.
- Metoclopramide, domperidone or other drugs to stop

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feeling or being sick.

- Zidovudine, didanosine or stavudine for the treatment of HIV infections.
- Drugs for migraine headaches.
- Drugs for high blood pressure (“alpha blockers”).
- Cannabidiol (a medicine used to treat seizures).
- Gabapentin and pregabalin (medicines used to treat epilepsy, nerve pain or anxiety), can increase the risk of opioid overdose, respiratory depression (breathing difficulties) and may be life-threatening.
- Fluconazole (used for treating infections)

The doctor may need to increase the dose of Methadone if taking these medicines:

- Rifampicin for tuberculosis.
- Phenytoin, Phenobarbital or Carbamazepine for epilepsy.
- Some drugs used for the treatment of HIV infection including Nevirapine, efavirenz and abacavir.
- Drugs which make the urine more acid, including ammonium chloride.
- Metamizole, a medicine used to treat pain and fever.

The doctor may need to reduce the dose of Methadone if taking these medicines:

- Other Methadone products or buprenorphine.
- Cimetidine for stomach ulcers or heartburn.
- Drugs for the treatment of HIV infection (known as CYP 3A4 inhibitors).
- The antibiotic medicine Ciprofloxacin.
- Medicines for fungal infections.
- Drugs which make the urine more alkaline, including potassium citrate.
- Fluvoxamine, a medicine used to treat depression.

Ask your doctor if you are unsure if any of these apply.

Pregnancy and breast feeding

Do not take this medicine 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 this medicine during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take this medicine while you are breastfeeding as methadone passes into breast milk and will affect your baby.

Talk to your doctor if you are breastfeeding or thinking of breastfeeding 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.

Driving and using machinery

This medicine may make you drowsy. If affected do not drive or operate machinery. People are affected differently so your doctor will advise you when it is safe to drive again.

The 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 of this medicine

This medicine contains:

- 1.04mg benzoic acid per 10ml dose.
- 99.5mg propylene glycol per 10ml dose.
- 2.8g sorbitol per 10ml dose. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.
- A colouring agent (E110) which may cause allergic reactions.
- less than 1mmol (23mg) sodium per 10ml dose, that is to say essentially ‘sodium free’.

3. How to take the medicine

This medicine has been prescribed for you personally. Do not pass it on to others as it may harm them.

Your prescriber should discuss your treatment and whether you need to continue taking this product 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.

Dose: Always take your medicine as prescribed by your doctor. The usual starting dose is 2 to 4 x 5ml spoonfuls by mouth daily, but doctors sometimes prescribe different doses to this. Follow the doctor’s instructions carefully. The dose should be taken all at once and preferably at the same time every day.

Use in children

Methadone is not suitable for children as they may be at greater risk from its effects (serious risk of toxicity).

If you take more medicine than you should see a doctor straight away.

If you take too much methadone you can experience the following:

- It can result in low blood sugar.

- A brain disorder (known as toxic leukoencephalopathy).

Effects when taken with alcohol or illegal substances

The risk of overdose and serious harm is greatly increased if taken with alcohol, heroin and/or other illegal substances. Do not mix these with your Methadone.

If you stop taking Methadone 1mg/ml

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.

4. Possible side effects

Like all medicines, Methadone 1mg/ml can have side effects although not everybody gets them.

Important side effects:

If you think you have the following serious side effects or symptoms, stop taking this medicine immediately and see a doctor straight away.

- Shallow breathing. This may lead to unconsciousness and death.

An allergic reaction which may include:

- Swelling of your face, lips, tongue or throat or difficulty breathing or swallowing
- Severe itching of your skin with raised lumps or rash.

Other possible side effects(frequency not known):

- Pinpoint pupils.
- Eye disorders in newborn babies.
- Low blood pressure on standing up, facial flushing.
- Worsening of existing asthma.
- Nausea, vomiting, constipation and dry mouth.
- Hallucinations, confusion, mood changes, anxiety, depression, lower sexual urge or desire.
- Increase in pressure within the head, particularly if pressure is already raised for other reasons, dizziness/vertigo, headache and drowsiness.
- Difficulty in passing water (urine), passing less water (urine) than usual.
- Reduction in the body’s normal production of adrenal hormones.
- Low body heat (hypothermia).
- Abnormal rapid, slow, or irregular heartbeat.
- Pain in the lower back and abdomen caused by muscle spasms.
- Dependence and addiction. Long term use may cause excessive sweating and irregularities in the make-up of the blood (increased number of white blood cells, increased protein or antibody levels). Erectile function, ejaculate volume and testosterone levels may be reduced in men. You can become dependent on Methadone 1mg/ml Oral Solution (for more information see section 2 Warnings and Precautions).
- Low blood sugar.
- Sleep apnoea (breathing pauses during sleep).

If any of the side effects gets serious or you notice any side effect not included above, please tell your doctor or pharmacist straight away. They will tell you what to do.

Drug Withdrawal

When you stop taking this medicine, 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 the medicine

Do not store above 25°C.

Keep this medicine out of the sight and reach of children. Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

Keep the medicine in a locked cupboard if possible.

Do not use the medicine after any expiry date which may appear on the label.

Medicines should not be disposed of via wastewater or household waste. Return any unused medicine to your pharmacist. These measures will help protect the environment.

6. Further information

What the medicine contains

The active substance is methadone hydrochloride 1mg per ml. The other ingredients are benzoic acid solution (E210, propylene glycol (E1520)), sorbitol solution (70% non-crystallising, E420), saccharin sodium, quinoline yellow (E104), green S dye (E142), sunset yellow dye (E110), and purified water.

What the medicine looks like

The medicine is a green coloured liquid.

Marketing Authorisation Holder and Manufacturer

Thornton and Ross Ltd., Huddersfield, HD7 5QH, England.

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