

PATIENT INFORMATION LEAFLET

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

(Methadone Hydrochloride 1mg/ml)

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.

In this leaflet

1. What is the medicine and what does it do?
2. Before you take the medicine
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4. Possible side effects
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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?

The product works to prevent withdrawal symptoms in people who are addicted to opioid drugs such as heroin. It is important that it is taken regularly to reduce the risk of withdrawal symptoms occurring.

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 moclobenide 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.

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

Children must not be given this medicine.

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.

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.
- Desipramine or other drugs for depression.
- Medicine for mental illness.
- Painkillers (other than Methadone).
- Sleeping tablets/mixtures or any other tranquillisers.
- Naloxone or naltrexone for drug or alcohol addiction.
- Metoclopramide or domperidone to stop feeling or being sick.
- Zidovudine, didanosine or stavudine for the treatment of HIV 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.

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

When pregnant it is especially important that you follow the instruction for treatment given by your doctor or clinic. Do not use this medicine whilst in labour. Talk to your doctor before breast feeding.

Use by children (Age 12 and below)

Children should not take this medicine as they may be at greater risk from its effects.

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.

Turn over ↗

Important information about some of the ingredients of this medicine

This medicine contains small amounts of ethanol (alcohol), less than 100mg per 5ml. It contains colouring agent (E110) which may cause allergic reactions. It also contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

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.

If you take too much see a doctor straight away.

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.

Effects when treatment is stopped

Stopping this medication abruptly will cause side effects, possibly severe. Follow the doctor's instructions carefully for coming off this medicine gradually.

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:

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

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.

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

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 out of the sight and reach of children.

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), sorbitol solution (70% non-crystallising), 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.

This leaflet was last revised in May 2016