Rosemont®

Patient Information Leaflet

Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution

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 of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution is and what it is used for
2. What you need to know before you take Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution
3. How to take Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution
4. Possible side effects
5. How to store Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution
6. Contents of the pack and other information

1. What Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution is and what it is used for

The name of your medicine is Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution (referred to as Methadone Solution in this leaflet). It contains methadone hydrochloride.

This medicine has been prescribed for you to treat opioid drug addiction or moderate to severe pain. It contains 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 discussed how long you will be taking it for, when it is appropriate to stop and how to do this safely.

2. What you need to know before you take Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution

Do not take Methadone Solution and tell your doctor if:
- you are allergic to methadone or any other ingredients of this medicine (listed in section 6). An allergic reaction can include a rash, itching or shortness of breath.
- you have severe breathing problems or a history of asthma. You must not use this medicine during an asthma attack. If you give this medicine to yourself (self-administration), wait until the asthma attack has passed and you are fully recovered.
- 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 Monoamine Oxidase Inhibitors (MAOIs) used to treat depression or if you have taken a MAOI medicine in the past two weeks (see 'Other medicines and Methadone Solution')
- you are dependent on any other drugs.
- you are in labour.
- you have phaeochromocytoma, a tumour of the adrenal glands.
- you have a bowel disorder known as paralytic ileus.

Children must **not** be given this medicine.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking methadone.

Warnings and precautions

Talk to your doctor or pharmacist or nurse if you experience any of the following symptoms while taking Methadone Solution:
- Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) or the biliary tract system.
- Pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Talk to your doctor before taking Methadone Solution if:
- you have liver or kidney problems
- you have problems with your gallbladder and bile duct
- you have epilepsy
- you have low thyroid function (hypothyroid)
- you have problems with your adrenal glands. These are linked to your kidneys
- you have an enlarged prostate gland
- you have low blood pressure
- you are in shock
- you have a muscle weakness disease called myasthenia gravis
- you have bowel problems
- you have a history of irregular heartbeat
- you have a history of heart disease
- you have a family history of people dying suddenly without cause
- you have low potassium, sodium or magnesium levels
- you are pregnant or breast-feeding
- you are extremely ill or an older person. You may be more sensitive to the medicine
- you are taking medicines called CNS depressants to treat anxiety, acute stress and panic attacks
- you have 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.

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 (amenorrhea).

Talk to your prescriber before taking this medicine for pain relief if you:
- have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- feel you need to take more of Methadone Solution to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking methadone.

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 can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

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. When used for the treatment of pain, you might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain

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 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 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 Solution).

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

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

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.

Sleep-related breathing disorders

Methadone 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 Solution

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines bought without a prescription, including herbal medicines. This is because methadone can affect the way some other medicines work. Also, some medicines can affect the way methadone works.

The risk of side effects increases, if you take methadone at the same time as 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).

You must **not** take Methadone Solution:
- at the same time or within 2 weeks of taking Monoamine Oxidase Inhibitors (MAOIs).

Some medicines can increase the risk of heart problems when used with Methadone Solution

Talk to your doctor before taking Methadone Solution if you are taking:
- medicines for heart problems such as verapamil and enalapril
- medicines which affect electrolyte balance such as diuretics (water tablets) or lithium.

Tell your doctor if you are taking any of the following medicines:
- medicines that dull your senses such as:
  - medicines to help you sleep (including anaesthetics)
  - medicines to calm you down called tranquillisers
- serotonergic medicines used to treat migraine, such as sumatriptan
- cimetidine, used to treat stomach ulcers
- rifampicin, used to treat tuberculosis (TB)
- medicines used to treat epilepsy such as phenytoin, carbamazepine, phenobarbital and primidone
- medicines that make your urine acidic such as ascorbic acid (vitamin C)
- narcotic painkillers such as codeine and pentazocine
- naloxone used to reverse the effects of opioid drugs
- medicines used to stop opioid drugs working such as naltrexone and buprenorphine
- medicines used to treat HIV such as nevirapine, efavirenz, abacavir and nelfinavir. The doctor may have to change the amount of methadone you take whilst on these medicines
- antibiotics such as ciprofloxacin or macrolide antibiotics for example erythromycin
- medicines used to treat fungal infections such as ketoconazole or fluconazole
- St. John's Wort - a herbal preparation for depression
- cyclizine, domperidone and metoclopramide, or serotonergic anti-emetics medicines such as ondansetron, used to treat nausea and vomiting
- medicines used to treat Parkinson's disease and atropine
- mexiletine used to treat unusual heart rhythms
- lofexidine or clonidine, used to treat withdrawal effects
- other opioid type drugs e.g. morphine
- medicines used to treat pain and fever such as metamizole
- 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.

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The use of Methadone Solution at the same time as 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, taking Methadone Solution and sedative medicines at the same time should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Methadone Solution together with sedative medicines the dose and duration of taking both treatments together 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 if you experience such symptoms.

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.
If any of the above apply to you, talk to your doctor before taking Methadone Solution.

Methadone Solution with food and drink
Do not drink alcohol whilst taking Methadone Solution. This is because Methadone Solution can make you feel sleepy and drinking alcohol will make you even more sleepy.
Grapefruit juice may effect how your Methadone solution works.

Pregnancy and Breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine

- take care if you are taking a pregnancy test as the methadone may interfere with the results.
- you should not take this medicine whilst you are in labour
- talk to your doctor if you are breast-feeding 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
- **Do not take** Methadone 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 solution during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
- Some studies have reported birth defects or neurodevelopmental problems (problems with early childhood development) in children born to mothers who used methadone during pregnancy to treat opioid addiction. However, it is not possible to determine if this is caused by methadone use or other factors such as the health of the mother and social and environmental conditions associated with opioid addiction.

Driving and using machines
Methadone solution can severely affect your ability to drive or use machines as it may make you sleepy or dizzy. You should only start doing these activities again with the permission of your doctor.

- **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.

Methadone Solution contains methyl and propyl parahydroxybenzoates, liquid maltitol and propylene glycol:

- methyl (E218) and propyl parahydroxybenzoates (E216). These may cause allergic reactions (possibly delayed)
- liquid maltitol (E965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Liquid maltitol may have a mild laxative effect and has a calorific value of 2.3kcal/g.
- propylene glycol (E1520). This medicine contains 103.7mg propylene glycol per 5ml. If you are pregnant, breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to take Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using methadone, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop taking methadone).
They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Taking this medicine

- this medicine contains 1mg of methadone in each 1ml.
- take this medicine by mouth.

Dose
Adults
For addiction

- the starting dose is 10mg to 20mg (10ml to 20ml) each day.
- the doctor can increase this to 40mg to 60mg (40ml to 60ml) each day.

For pain

- the usual dose is 5mg to 10mg (5ml to 10ml) every 6 to 8 hours.
- the dose may be changed by your doctor.

Older people and very ill people

- if you have to have repeated doses of this medicine, the doctor may want to monitor you more closely.

Use in children
Children must not take this medicine.

If you take more Methadone Solution than you should

- if you take more of this medicine than you should, talk to a doctor or go to your nearest hospital straight away. Take the medicine pack with you.
- the signs you may notice are difficulty in breathing; feeling very drowsy which may lead to a stupor or coma; very small pupils; cold and clammy skin; a very slow pulse rate; low blood pressure and muscle weakness. In extreme cases, you may stop breathing, your blood flow may stop, you may have a heart attack which could lead to death.
- it can result in low blood sugar.
- A brain disorder (known as toxic leukoencephalopathy)

If you forget to take Methadone Solution

- if you forget a dose do not take it. Wait until the next dose is due and take only that amount.
- do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Methadone 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Methadone Solution can cause side effects although not everybody gets them.

Serious side effects
Stop taking this medicine and see a doctor straight away if you have an allergic reaction to Methadone Solution.
An allergic reaction may include:

- swelling of your face, lips, tongue or throat or difficulty breathing or swallowing
- severe itching of your skin with raised lumps.

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 becomes slow and shallow
- worsening of the pressure inside your head if you already have this condition following an injury to your brain or brain disease.

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.

Other side effects
Tell your doctor if you get any of these side effects:
Very common (affects more than 1 in 10 people)

- feeling sick (nausea) or being sick (vomiting).

Common (affects less than 1 in 10 people)

- feeling weak, tired
- weight gain
- water retention
- constipation
- rash, that may appear and disappear
- sweating a lot more than usual
- blurred vision, small pupils, dry eyes
- feeling of dizziness, spinning sensation
- changes in your mood, feeling "high" or over excited, feeling drowsy
- seeing or hearing things that are not there (hallucinations)

Uncommon (affects less than 1 in 100 people)

- feeling dizzy, particularly when standing up. This may be a sign that you have low blood pressure
- headache
- feeling down (dysphoria), agitation, confusion, difficulty sleeping
- itching, rashes
- dry mouth or nose, inflammation of the tongue, facial flushing
- breast growth and production of breast milk
- difficulty in passing water (urine), pain in the lower back and abdomen caused by muscle spasms
- low body heat (hypothermia)
- lower sexual urge or desire
- painful periods or lack of periods
- addiction to this medicine
- build-up of fluid in the lungs
- disorder of the biliary part of the digestive system (bile duct dyskinesis).

Not known (frequency cannot be estimated from the available data)

- reduction in blood platelets, which increase the risk of bleeding or bruising
- high prolactin levels in the blood
- rapid, uncontrollable movements of the eyes
- low blood sugar
- dependence and addiction (see section 'How do I know if I am addicted?')
- You can become dependent on Methadone (for more information see section 2 Warnings and Precautions)
- Sleep apnoea (breathing pauses during sleep) (for more information see section 2 Sleep-related breathing disorders).
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

Drug Withdrawal
When you stop taking Methadone 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.

How do I know if I am addicted?
If you notice any of the following signs whilst taking Methadone Solution, it could be a sign that you have become addicted.

- you need to take the medicine for longer than advised by your prescriber
- you feel you need to use more than the recommended dose
- you are using the medicine for reasons other than prescribed
- when you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

The following side effects have also been reported.

- loss of appetite
- swollen arms and legs. This may be a sign of your body holding onto more water than usual
- low potassium and magnesium which will be found by blood tests
- eye and eyesight problems in babies and young children born to mothers who used methadone during pregnancy. This may mean your child needs more frequent eye-tests
- reduction in the body's normal production of adrenal and sexual hormones.

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 solution.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution

- Keep 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.
- Store below 25°C. Protect from light.
- Do not use after the expiry date (month, year) stated on the label and carton.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not use Methadone Solution if you notice anything wrong with the medicine. Talk to your pharmacist.
- 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.

6. Contents of the pack and other information

What Methadone Solution contains

- The active ingredient is methadone hydrochloride.
- The other ingredients are methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), propylene glycol (E1520), caramel (E150), liquid maltitol (E965), patent blue (E131) and purified water.

What Methadone Solution looks like and contents of the pack

- A green solution.

It comes in a brown glass bottle holding 50ml, 100ml or 500ml of solution.

Marketing Authorisation Holder and Manufacturer
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