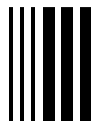


## Methadose® 10mg/1ml Oral Concentrate Methadone Hydrochloride

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 Methadose is and what it is used for
2. What you need to know before you take Methadose
3. How to take Methadose
4. Possible side effects
5. How to store Methadose
6. Contents of the pack and other information

## 1. What Methadose is and what it is used for

The name of your medicine is Methadose 10mg/1ml. It contains methadone hydrochloride. This medicine has been prescribed for you for opioid drug addiction. 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 explained 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 Methadose

**Do not take Methadose 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 Methadose')
- 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 Methadose.

### Warnings and precautions

Talk to your doctor before taking Methadose 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 (amenorrhoea).

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

### 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 Methadose 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 Methadose 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 Methadose, 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 Methadose).

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.

### Sleep-related breathing disorders

Methadose 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 Methadose

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 Methadose can affect the way some other medicines work. Also some medicines can affect the way Methadose 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 Methadose:

- 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 Methadose. Talk to your doctor before taking Methadose 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 tranquilisers
- 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.

The use of Methadose 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 Methadose and sedative medicines at the same time should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Methadose 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 Methadose.

### Methadose with food and drink

Do not drink alcohol whilst taking Methadose. This is because Methadose can make you feel sleepy and drinking alcohol will make you even more sleepy.

Grapefruit juice may affect how your Methadose 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** Methadose 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 Methadose during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

### Driving and using machines

Methadose 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.

### Methadose contains methyl and propyl parahydroxybenzoates and propylene glycol:

- methyl (E218) and propyl parahydroxybenzoates (E216). These may cause allergic reactions (possibly delayed)
- propylene glycol (E1520). This medicine contains 155.6mg 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.

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### 3. How to take Methadose

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

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

#### Taking this medicine

- this medicine contains 10mg of methadone in each 1ml
- take this medicine by mouth
- this medicine is intended for use with another liquid to dilute it with (diluent).

Your pharmacist or prescriber should dilute the concentrate to provide the appropriate concentration of drug in a 5ml dose.

#### Dose

##### Adults

- the starting dose is 10mg to 20mg (1ml to 2ml) each day
- the doctor can increase this to 40mg to 60mg (4ml to 6ml) each day.

##### 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 Methadose 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 Methadose

- 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 Methadose

**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, Methadose 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 Methadose.**

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 dyskinesia).

**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. You can become dependent on Methadose (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).

#### Drug Withdrawal

When you stop taking Methadose, 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.

**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
- 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 Methadose.

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](http://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 Methadose

- 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 but not in a refrigerator
- Take back to the pharmacy 3 months after you first open it or 3 months after it has been diluted
- 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 Methadose 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 Methadose 10mg/1ml Oral Concentrate contains

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

#### What Methadose 10mg/1ml Oral Concentrate looks like and contents of the pack

- Before and after dilution: a blue liquid

It comes in a brown glass bottle holding 150ml or 500ml of solution.

#### Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd., Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in 07/2023.