

Package leaflet: Information for the user

Metadon Pharmadone 10 mg oral solution
Metadon Pharmadone 25 mg oral solution
Metadon Pharmadone 60 mg oral solution
Metadon Pharmadone 70 mg oral solution
Metadon Pharmadone 80 mg oral solution
Metadon Pharmadone 90 mg oral solution
Metadon Pharmadone 100 mg oral solution
Metadon Pharmadone 110 mg oral solution
Metadon Pharmadone 120 mg oral solution

methadone hydrochloride

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

1. What Metadon Pharmadone is and what it is used for

Metadon Pharmadone is used for the treatment of opioid-related drug dependency. Methadone blocks the body's opioid receptor, and suppresses the symptoms of withdrawal. Methadone treatment is supposed to take place together with psychological treatment and social follow-up. All methadone treatment shall be according to national guidelines.

2. What you need to know before you take Metadon Pharmadone

Do not take Metadon Pharmadone:

- if you are allergic to methadone or any of the other ingredients of this medicine (listed in section 6).
- if you have severe respiratory depression, with slow and shallow breathing, or other acute breathing difficulties.
- if you are treated with opioid agonists/antagonists.
- if you are taking monoamino-oxidase inhibitor (MAO-inhibitor), used to treat depression, Parkinson disease, or have taken it within the last two weeks.

Metadon Pharmadone must not be given to children.

Warnings and precautions

Talk to your doctor before using Metadon Pharmadone:

- if you get acute asthma attack or reduced lung capacity due to any lung diseases, e.g. asthma, chronic obstructive airways disease and decreased lung volume.
- if you have reduced liver or kidney function or if you have kidney- or gallstones.

- if you have serious heart problems such as ischemic heart disease, problems with cardiac rhythm or low levels of potassium or magnesium in the blood.
- if you are treated with certain heart medicines, see Other medicines and Metadon Pharmadone.
- if you have inflammatory or obstructive bowel disease with abdominal pain, diarrhoea or constipation.
- if you have an enlarged prostate gland or narrowing of the urethra.
- if you have problems with the thyroid gland.
- if you have head injury and increased pressure in the skull - you might get bad headaches.
- if you are elderly.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Metadon Pharmadone:

- 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).

Co-administration of opioid type drugs, barbiturates, benzodiazepines or other drugs with a strong sedative effect should be avoided as it can increase the effect and side effects of 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 Metadon Pharmadone 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 Metadon Pharmadone 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 Metadon Pharmadone, 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 Metadon Pharmadone).

Sleep-related breathing disorders

Metadon Pharmadone 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.

Children

Children are more sensitive to methadone than adults. Poisoning can take place even at very low dose. To avoid that children mistakenly can take methadone when using it at home, store it in a secure place and keep out of the reach of children.

Other medicines and Metadon Pharmadone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Pay special attention to:

- medicines that have an effect on your mental state (e.g. thioridazine, phenothiazines, haloperidol and sertindole)
- medicines used to treat heart diseases (verapamil, quinidine)
- medicines used to treat depression known as monoamine oxidase inhibitors (MAOIs), particularly if you have taken them within the last two weeks
- anti-inflammatory and immunosuppressants (e.g. dexamethasone and cyclosporine)
- antiviral drugs including some medicines used to treat HIV e.g. nevirapine, zidovudine, efavirenz, nelfinavir, ritonavir, abacavir, didanoside and stavudine
- macrolide antibiotics (medicines used to treat bacterial infections) such as clarithromycin, telithromycin and erythromycin
- cimetidine (a medicine used to treat stomach ulcers)
- antifungals (medicines used to treat fungal infections) such as ketoconazole, itraconazole and fluconazole
- naloxone (a medicine used to treat difficulties with breathing)
- medicines used to treat addiction e.g. naltrexone and buprenorphine
- rifampicin (a medicine used to treat tuberculosis)
- medicines used to treat epilepsy (e.g. phenytoin, phenobarbital and carbamazepine)
- vitamin tablets containing vitamin C
- medicines used to treat diarrhoea (loperamide, diphenoxylate)
- medicines and products that make your urine more acid, e.g. ammonium chloride (salmiak)
- diuretic medicines (spironolactone)
- medicines that make you feel sleepy
- herbal medicines containing St John's Wort
- 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 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 (e.g. sotalol, amiodarone and flecainide).

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, at the start of treatment, to monitor your heart with an electrocardiogram (ECG) to ensure that these effects do not occur.

Methadone can also affect some blood and urine tests. Tell your doctor that you are taking methadone before any test is performed.

Metadon Pharmadone with food and drink

You must not drink alcohol while taking Metadon Pharmadone since this can cause serious side effects. Do not drink grapefruit juice while you are taking Metadon Pharmadone as it may alter the effect of the medicinal product.

Pregnancy and breast-feeding

If you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

The foetus may be affected if methadone is used during pregnancy. Do not use Metadon Pharmadone whilst you are in labour unless prescribed by your doctor.

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.

Driving and using machines

Methadone affects the coordination between the brain and body movements, so the ability to drive or use machines may be severely affected until your medication has been stabilised at a certain dose level. Therefore you should not drive or use machines during the initial treatment period. How long it takes before you can drive or use machines is to a large extent individual, so you should decide this together with your doctor.

Metadon Pharmadone contains sucrose, glucose and methylparahydroxybensate

Sucrose:

Contains 11 g sucrose per dose. The amount of sugar should be taken into account if you have diabetes mellitus. If you cannot tolerate some sugars, tell your doctor before taking this medicine.

Glucose:

If you cannot tolerate some sugars, tell your doctor before taking this medicine.

Methylparahydroxybensate:

May cause allergic reactions (possible delayed).

3. How to take Metadon Pharmadone

Always take this medicine exactly as your doctor has told you. The dose is individually determined for you by the doctor. Check with your doctor or pharmacist if you are not sure.

Metadon Pharmadone is an oral solution and must only be taken by mouth. Your doctor adjusts the dose individually for you, he/she will tell you how much Metadon Pharmadone you need to take, and how often you need to take it. It is important that you do not take more than the dose agreed with your doctor.

Use in children

Metadon Pharmadone must NOT be given to children. There is a serious risk of poisoning. Remember to keep this medicine out of reach of children, in a safe place.

If you take more Metadon Pharmadone than you should:

If you have taken more medicinal product than you should or if for example a child has taken the medicine by mistake, you should seek medical advice.

Signs of overdose methadone may be small pupils, drowsiness, paleness, moist skin, low body temperature, hearingloss, breathing difficulties and coma. It can result in low blood sugar. At severe overdosage the following symptoms may occur: short respiratory arrest, low blood pressure, slow pulse, shock, heart effects, fluid in the lungs, seizures, muscle weakness, renal failure, irregular heart rhythm and death. Children and elderly are more sensitive to this medicine. Contact your doctor if any of the above symptoms occur. If you take too much methadone you can experience a brain disorder (known as toxic leukoencephalopathy).

If you forget to take Metadon Pharmadone

Do not take a double dose to make up for a forgotten dose. Contact your doctor or pharmacist for advice.

If you stop taking Metadon Pharmadone

Do not stop taking this medicine abruptly; you should only stop the treatment in close contact with your doctor. An abrupt stop may cause withdrawal symptoms as restlessness, drowsiness, anxiety, tremulousness, nausea, vomiting or diarrhoea.

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

4. Possible side effects

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

Very common side effects (may affect more than 1 in 10 people)

- Feeling sick (nausea, vomiting) (mostly patients treated at home).

Common side effects (may affect up to 1 in 10 people)

- Weight increase
- Accumulation of water in the body
- Constipation
- Excitement (euphoria) or seeing or hearing things that are not real (hallucinations)
- Feeling of dizziness or spinning, feeling tired or sleepy
- Pin point pupils, blurred vision
- Skin rash
- Sweating

After long term use of methadone, the side effects often gradually reduced, but obstipation and sweating remains.

Uncommon side effects (may affect up to 1 in 100 people)

- Loss of appetite
- Breathing difficulties (with cough)
- Dry mouth
- Inflammation in the tongue
- Depressed mood (dysphoria), physical and mental unrest (agitation)
- Sleep disturbance
- Confusion
- Decreased sexual drive, difficulties in achieving or maintaining erection
- Menstrual disorders
- Headache
- Fainting and low blood pressure
- Itching, hives, sometimes bleeding hives
- Seizure in the bile ducts (gives stomach ache)
- Facial flush
- Difficulties to pass water

Rare side effects (may affect up to 1 in 1000 people)

- Heart problems, slower pulse, palpitation

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

- Too low level of potassium or magnesium in the blood
- Decreased number of blood platelets in the blood
- Low blood sugar
- You can become dependent on Metadon Pharmadone (for more information see section 2 Warnings and Precautions)

- Sleep apnoea (breathing pauses during sleep)

When taken for a long period of time, it is possible that you may become dependent. The withdrawal effects are analogue to that of morphine and heroin, but are less intensive but lasts longer.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Metadon Pharmadone

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.

Do not use this medicine after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.

Do not use Metadon Pharmadone if the cap seal is broken.

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. Content of the pack and other information

What Metadon Pharmadone contains

- The active substance is methadone hydrochloride
- The other ingredients are sucrose, glucose, raspberry aroma, purified water and methylparahydroxybensate (E218).

What Metadon Pharmadone looks like and contents of the pack

Clear, transparent solution which is available in white plastic bottles, sealed with a children safe, breaking sealed cap. The bottle contains 50 ml oral solution.

Pack sizes: 1 bottle (all strengths) and 7 bottles (1x7) (60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 110 mg and 120 mg).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

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