

Package leaflet: Information for the patient

Metadon Nordic Drugs oral solution: 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190 and 200 mg

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

1. What Metadon Nordic Drugs is and what it is used for

Methadone is a synthetic opiate (a morphine-like medicine) used for treatment of opiate dependent patients. The treatment should be given together with medical and psychological treatment and social rehabilitation.

2. What you need to know before you take Metadon Nordic Drugs

Do not take Metadon Nordic Drugs:

- if you are allergic to methadone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you use or have used monoamine oxidase inhibitors (MAOIs - medicinal products used in the treatment of depression and Parkinson's disease) within the last two weeks
- if you suffer from breathing difficulties

Metadon Nordic Drugs must NOT be given to children

Warnings and precautions

Talk to your doctor or pharmacist before taking Metadon Nordic Drugs if you:

- have acute asthma attacks
- are suffering from lung disease or breathing difficulties
- have liver or kidney problems (including kidney stones and gallstones)
- suffer from heart problems
- have an under-active thyroid gland or skin and tissues disorders
- have an enlarged prostate gland or narrowed urethra
- have suffered from a head injury and the pressure inside your brain is higher than it should be (check this with your doctor) - you might get bad headaches
- are being treated for drug addiction or opioid overdose
- have difficulty in passing urine

- have abdominal pain, diarrhoea or constipation
- have low oxygen level or high carbon dioxide level in the blood
- are taking other medicines of opioid type (painkiller) such as morphine and pentazocine
- are taking medicines that make you relax and help you to sleep (barbiturates and benzodiazepines)

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 Nordic Drugs 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 Nordic Drugs 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 Nordic Drugs, 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.

Sleep-related breathing disorders

Metadon Nordic Drugs 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.

Methadone may affect the electrical signals which control your heart contractions, particularly at high doses. Tell your doctor if you have a history of heart problems.

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

- 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.

- 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.

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).

Children

Children are more sensitive to methadone than adults; that is why poisoning may occur at very low doses. To avoid unintentional intake of methadone by children when it is taken home, keep it in a safe place where children cannot reach it.

Other medicines and Metadon Nordic Drugs

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
- other medicines to treat depression (e.g. imipramine, desipramine, nefazodone, fluoxetine, fluvoxamine, paroxetine and sertraline)
- 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 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.

Other medicines you may be taking can also affect the heart (e.g. sotalol, amiodarone and flecainide).

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)

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 Nordic Drugs with food, drink and alcohol

You must not drink alcohol while you are taking Metadon Nordic Drugs as this could cause serious side effects. Do not drink grapefruit juice during treatment with Metadon Nordic Drugs, as it may alter the effect of the medicinal product.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Metadon Nordic Drugs should not be taken during labour.

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.

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

Metadon affects the coordination of brain and body movement, and the ability to drive or use machinery may be severely affected until your medication has been stabilised at a certain dosage level. You should therefore not drive or use machinery during the initial period of treatment. The time period before driving or using machinery is individual and should be decided together with your doctor.

Metadon Nordic Drugs contains sucrose, glucose and methylparahydroxybenzoate

The content of sucrose 11 g/dose and glucose 2.5 mg/dose should be taken into consideration in patients with diabetes mellitus. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

The preservative methylparahydroxybenzoate (E 218) may cause allergic reactions (sometimes delayed).

3. How to take Metadon Nordic Drugs

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

You must only take Metadon Nordic Drugs by mouth. You shall under no circumstances inject this product, as injecting may cause serious and permanent damage to your body with possible fatal consequences.

Your doctor will tell you how much Metadon Nordic Drugs 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.

Adults

The recommended starting dose is 10-30 mg a day. The dose will be slowly increased until you show no signs of withdrawal or intoxication. The usual dose is 60-120 mg a day. Your doctor will decide what dose you need and when to reduce the dose.

Elderly and illness patients

Extra caution must be taken if you are elderly, have an illness or have liver or kidney problems.

Use in children

Metadon Nordic Drugs 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 Nordic Drugs than you should

If you take too much Metadon Nordic Drugs, you may experience the following:

- difficulty breathing
- extreme sleepiness, fainting or coma
- low blood sugar
- pin point pupils
- muscle weakness
- cold and clammy skin
- slow heartbeat, low blood pressure, heart attack or shock
- in severe cases death may occur
- a brain disorder (known as toxic leukoencephalopathy)

In the event of overdose you should seek immediate medical care, even if you feel well, since you may be suffering from methadone poisoning.

If you forget to take Metadon Nordic Drugs

If you should miss a dose during a course of treatment it is important that, you take the dose as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, and wait until the next scheduled dose. **DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.**

4. Possible side effects

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

Side effects which may occur include:

Very common: may affect more than 1 in 10 people

- feeling sick or being sick

Common: may affect up to 1 in 10 people

- weight increase
- water retention in your body
- constipation
- feeling high (euphoria)
- seeing or hearing things that are not real (hallucinations)
- feeling of dizziness or spinning
- blurred vision
- pin point pupils
- feeling sleepy
- skin rash
- sweating
- feeling tired

Uncommon: may affect up to 1 in 100 people

- loss of appetite
- breathing difficulty (including with cough)
- dry mouth
- inflammation of tongue
- feeling down (dysphoria)
- agitation
- difficulty sleeping
- confusion
- reduction of sex drive
- headache
- fainting
- low blood pressure

- itching
- hives
- swelling of legs
- weakness
- severe water retention in your body (oedema)
- bile duct spasm (abdominal pain)
- facial flush
- difficulty in passing urine
- difficulty achieving or maintaining an erection
- disturbances in menstruation

Rare: may affect up to 1 in 1,000 people

- heart problems
- slower heart beat
- feeling your heart beat (palpitations)

Not known: frequency cannot be estimated from the available data

- deficiency of potassium or magnesium in blood
- lower levels of platelets in blood
- low blood sugar
- you can become dependent on Metadon Nordic Drugs (for more information see section 2 Warnings and precautions)
- breathing pauses during sleep (sleep apnoea)
- 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.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metadon Nordic Drugs

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 bottle or carton after EXP. The expiry date refers to the last day of that month.

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 Metadon Nordic Drugs contains

- The active substance is methadone hydrochloride.
1 dose (50 ml) contains 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190 or 200 mg methadone hydrochloride.
- The other ingredients are sucrose, glucose, methyl parahydroxybenzoate (E 218), raspberry aroma, water.

What Metadon Nordic Drugs looks like and contents of the pack

Metadon Nordic Drugs is a clear, transparent liquid supplied in a plastic bottle with white child resistant cap. The bottle contains 50 ml solution. Single bottles or packs of 7 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Nordic Drugs AB
Box 300 35
200 61 Limhamn
Sweden

Manufacturer

Apotek Produktion & Laboratorier AB, Box 17, 201 20 Malmö, Sweden

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden: Metadon Nordic Drugs
Finland: Metadon Nordic Drugs
Norway: Metadon Nordic Drugs

This leaflet was last revised in 11 June 2026

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The following information is intended for healthcare professionals only:

Bottles containing doses above 150 mg should be handled by health care professionals only (160, 170, 180, 190, 200 mg single dose).