

D05994

PACKAGE LEAFLET: INFORMATION FOR THE USER

Methadone 5mg Tablets

Methadone Hydrochloride

Read all of this leaflet carefully before you start taking Methadone Hydrochloride Tablets because it contains important information for you.

- Keep this leaflet. You may need to read it again
If you have any further questions, please 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 Tablets are and what they are used for
2. What you need to know before you take Methadone Tablets
3. How to take Methadone Tablets
4. Possible side effects
5. How to store Methadone Tablets
6. Contents of the pack and other information

This medicine contains methadone, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

1. What Methadone Tablets are and what they are used for

This medicine has been prescribed for you for treatment of moderate to severe pain. It contains methadone which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else.

2. What you need to know before you take Methadone Tablets

- Do not take Methadone Tablets if:
You are allergic to methadone or any of the ingredients of this medicine (listed in section 6).
You have any problem with your breathing, any chronic lung disease or have an asthma attack.
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, or have recently stopped taking, a type of medicine called Monoamine Oxidase Inhibitors (MAOIs), including moclobemide which are used to treat depression, within the past two weeks.
You are in labour.
You have an acquired or inherited heart condition which is characterized by irregular heartbeats.
You have severe liver disease.
You suffer from sudden involuntary muscle contraction of the bile ducts and kidney.

Methadone Tablets are not suitable for children.

Warnings and precautions

Sleep-related breathing disorders
Methadone 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.

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 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, 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).

Talk to your doctor or pharmacist before taking Methadone Tablets if:

- You are extremely ill or an older person. You may be more sensitive to the medicine.
You have history of asthma or breathing difficulties.
You have bowel problems.
You have liver or kidney problems.
You have a history of convulsions, fits or epilepsy.
You have a history of low blood pressure.
You have a history of under-active thyroid gland, or problems with your adrenal glands.
You have a history of enlarged prostate gland.
Are or 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 tablets 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.

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.

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).

Methadone Tablets may affect the electrical signals which control your heart contractions, particularly at high doses.

Tell your doctor you have recognised risk factors for the heart condition 'QT prolongation' that include if:

- you have a history of heart problems
you have liver disease
you have any blood abnormalities such as low levels of potassium or magnesium
you have a history of sudden death in the family.

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

- 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.

Other medicines and Methadone Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

- Medicines used to treat addiction e.g. naltrexone.
Medicines used to treat epilepsy such as phenytoin and carbamazepine
Naloxone (a medicine used to treat an overdose of opioid medicines).
Antibiotics (medicines used to treat bacterial infections e.g. ciprofloxacin, erythromycin, telithromycin and clarithromycin).
Antifungals (medicines used to treat fungal infections) e.g. fluconazole, itraconazole, ketoconazole.
Medicines that make urine more acidic e.g. ammonium chloride and ascorbic acid.
Antiviral medicines including some medicines used to treat HIV e.g. nevirapine, zidovudine, delavirdine, lopinavir, saquinavir, didanosine, stavudine, efavirenz, nelfinavir, amprenavir and ritonavir.
Medicines used to treat depression including fluvoxamine, nefazodone, paroxetine, sertraline and fluoxetine or MAOIs including moclobemide, must not be taken at the same time or within 2 weeks of taking MAOIs.
CNS depressants (medicines that act on the brain and cause drowsiness or sleepiness).
St John's Wort - a herbal preparation for depression
Medicines used to treat heart irregularities e.g. quinidine, mexiletine, verapamil, amiodarone, sotalol, flecainide
Medicines that suppress the immune system e.g. ciclosporin, dexamethasone
Medicines used to treat certain mental and emotional conditions, (anti-psychotics) e.g. thioridazine, haloperidol, sertindole, and phenotiazines
Medicines used to treat high blood pressure e.g. spironolactone
Medicines used to treat diarrhoea e.g. loperamide
Medicines used to treat allergies e.g. diphenhydramine
Medicines used to treat tuberculosis e.g. rifampicin.
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 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. You must tell your doctor about any other medicines that you are taking as they may be dangerous if they are taken with Methadone tablets. 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. Concomitant use of Methadone tablets and 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, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Methadone tablets together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Continued overleaf

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 when experiencing such symptoms

Methadone Tablets with food and drink
You must not drink alcohol whilst you are taking Methadone Tablets as this could cause serious side effects. You are advised not to drink grapefruit juice whilst you are being treated with Methadone tablets as it could cause an overdose

Pregnancy, breast-feeding and fertility
If you are pregnant or breast feeding, think you maybe pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

Pregnancy
Do not take Methadone Tablets 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 Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

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.

Breast-feeding:
Do not take Methadone Tablets while you are breastfeeding as methadone passes into breast milk and will affect your baby.

Labour:
You should not take Methadone Tablets whilst you are in labour.

Driving and using machines
The ability to drive or use machinery may be severely affected during and after treatment with Methadone. You must not drive or use machinery until you are told that you can do so by your doctor.

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.

Important information about some of the ingredients

Methadone Tablets contain:
Lactose: if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Methadone Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important that you do not take more than the dose agreed with your doctor. You can become dependent on Methadone Tablets.

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). Also will outline how to gradually reduce the dose and stop taking the medicine.

Adults:
The recommended initial dose is 5-10mg (1 to 2 tablets) every 6 to 8 hours. The dose may be adjusted depending on the level of pain relief you need.

Elderly or ill:
If you are elderly or ill, your doctor will only prescribe repeated doses with caution.

Use in children and adolescents
Not recommended. There is a serious risk of poisoning. Remember to keep your medicine safely where children can not get it.

If you forget to take Methadone Tablets
During a course of treatment it is important that, should you miss a dose, you take the dose as soon as you remember. However, if it is almost time for you to take your next dose, miss the dose and wait until the next scheduled dose.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.

If you stop taking Methadone Tablets
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 take more Methadone Tablets than you should
If you take too many Methadone Tablets, you can experience the following:

- difficulty in breathing
extreme sleepiness, fainting or coma
pin point pupils
swelling and/or fluid accumulation in the lungs
low blood pressure
low blood sugar
a brain disorder (known as toxic leukoencephalopathy).

In the event of overdose you should seek medical assistance immediately even if you feel well as you may be suffering methadone poisoning.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Repeated use of Methadone tablets can result in tolerance and addiction.

Stop taking this medicine and see a doctor straight away if you get any of the following side effects:

- 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 become 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.
Severe itching of your skin with raised lumps
Low blood platelet count. Symptoms include bleeding or bruising more easily than normal

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

- Feeling sick (nausea) or being sick (vomiting)
Fluid retention due to slow metabolism
changes in your mood, feeling 'high' or over excited
seeing or hearing things that are not there (hallucinations)
low magnesium levels in the blood
drowsiness or sleepiness (sedation)
blurred vision
small pupils
dizziness, spinning sensation
constipation
rash
sweating
tiredness
weight increase

Uncommon (may affect up to 1 in 100 people):

- feeling tense and restless
addiction to medicines
agitation
inability to sleep
reduced sexual drive
disorientation
facial flushing
feeling dizzy, particularly when standing up. This may be a sign that you have low blood pressure
headache
fainting
build-up of fluid in the lungs
Dry mouth
Swollen, red, sore tongue
Swelling of the hip, knee, feet and ankle joints
Difficulty in passing water(urine), pain in the lower back and abdomen caused by muscle spasms
Lower sexual urge or desire
Painful periods or lack of periods
Unusual weakness (asthenia)
Itching
Hives
Uncontrollable twitching, jerking or writhing movement of the bile duct (bile duct dyskinesia)
Swelling of the hands, ankles or feet

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

- Loss of appetite
Low potassium and magnesium levels in the blood
High prolactin levels in the blood
Dependence and addiction (see section "How do I know if I am addicted?")
low blood sugar
You can become dependent on Methadone (for more information see section 2 Warnings and Precautions)
Sleep apnoea (breathing pauses during sleep).

Drug Withdrawal
When you stop taking Methadone Tablets, 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 tablets, 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

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 Website: 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 Tablets

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. The expiry date refers to the last date 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. Do not store above 25°C.

6. Contents of the pack and other information

What Methadone Tablets contain:
The active ingredient is Methadone Hydrochloride 5mg per tablet.

The other ingredients are lactose, maize starch, gelatin, glycerol and magnesium stearate.

What Methadone Tablets look like and the contents of the pack:
Methadone Tablets are plain white uncoated tablets with break line "MART 5" marking, supplied either in amber glass bottles, each containing 100 tablets or in plastic blister packs, each containing 50 tablets.

Marketing Authorisation Holder:
Macarthy Laboratories Ltd
T/A Martindale Pharma,
Bampton Road, Harold Hill,
Essex, RM3 8UG,
United Kingdom

Manufacturer:
Macarthy Laboratories Ltd
T/A Martindale Pharma,
Bampton Road, Harold Hill,
Essex, RM3 8UG,
United Kingdom

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Bampton Road, Harold Hill, Romford, RM3 8UG, UK

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