

Package leaflet: Information for the patient

Metadon 2care4 5 mg tablets

Metadon 2care4 10 mg tablets

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

1. What {Invented name} is and what it is used for

{Invented name} is a morphine-like medicinal product which is used in adults for:

- treating severe chronic pain which can be adequately managed only with opioid analgesics.
- substitution therapy in opiate dependent patients, given together with medical and psychological treatment and social rehabilitation.

2. What you need to know before you take {Invented name}

Do not take {Invented name}:

- if you are allergic to methadone or any of the other ingredients of this medicine (listed in section 6).
- if you use or have used a monoamino-oxidase inhibitor (MAO-inhibitor) within the last two weeks (medicine used in the treatment of depression and Parkinson's disease).
- if you have respiratory depression with slow and shallow breathing, or other acute breathing difficulties (acute obstructive airway disease).

Warnings and precautions

Talk to your doctor or pharmacist before taking {Invented name}, if you:

- get acute asthma attacks,
- suffer from lung disease or breathing difficulties,
- have a heart disorder or ischemic heart disease,
- have a liver disease or impaired liver function (including gallstones),
- have impaired kidney function (including kidney stones),
- have an underactive thyroid gland,
- have skin- or tissue diseases,
- have an enlarged prostate or narrowing of the urethra,
- have been affected by a head injury and the pressure in the brain is higher than it should be (check this with your doctor). You may be affected by a severe headache,
- are treated for drug addiction or overdosage of opioids,
- have difficulties to pass water,

- have stomach pains, diarrhoea or constipation,
- have a low oxygen level or high carbon dioxide level in the blood,
- take other medicines of opioid type (painkillers), such as morphine and pentazocine,
- take other medicines which gets you relaxed and help you go to sleep (barbiturates and benzodiazepines),
- have low levels of potassium or magnesium in the blood.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking {Invented name}:

- 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.
- Pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

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.

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 {Invented name} 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 {Invented name} 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 {Invented name}, 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 {Invented name}).

Sleep-related breathing disorders

{Invented name} 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.

{Invented name} may affect the electrical signals which operate the heart constrictions, especially at high doses. Tell your doctor if you have a history of heart problems.

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).

Elderly

Elderly patients have an increased risk of low blood pressure and fainting.

Children

{Invented name} MUST NOT be given to children. Children are more sensitive to methadone than adults. Therefore, poisoning may occur at very low doses. In order to avoid children taking methadone by mistake when you use it at home, methadone should be stored in a safe place, out of reach of children.

Other medicines and {Invented name}

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

- medicines that affect your mental state (e.g., thioridazine, perphenazine, risperidone, haloperidol and sertindole),
- medicines for treatment of ADHD (atomoxetine),
- medicines used to treat depression, known as monoamine-oxidase inhibitor (MAO-inhibitor), especially if you have taken them within the last two weeks. Also tell your doctor if you are using other antidepressant medicines (e.g., nefazodone, fluoxetine, fluvoxamine, paroxetine and sertraline),
- other medicines used to treat depression, known as tricyclic antidepressants (e.g., clomipramine, nortriptyline, desipramine),
- 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,
- medicines to treat heart diseases (verapamil, quinidine),
- antiarrhythmic agents (e.g., propafenone and flecainide) and beta receptor blocker (metoprolol),
- medicines to treat breast cancer (tamoxifen),
- anti-inflammatory and immunosuppressive medicines (e.g., dexamethasone and ciclosporin),
- antiviral medicines, including certain anti-HIV medicines e.g., nevirapine, zidovudine, efavirenz, nelfinavir, amprenavir, delavirdin, ritonavir, combination of lopinavir/ritonavir, combination of ritonavir/saquinavir, didanosine and stavudine,
- antibiotics of macrolide type (medicines to treat bacterial infections) such as clarithromycin, telithromycin and erythromycin,
- rifampicin (a medicine to treat tuberculosis or TBC),
- antifungal medicines such as ketoconazole, itraconazole and fluconazole,
- cimetidine (medicine to treat stomach ulcer),
- naloxone (a medicine to treat breathing difficulties),
- medicines to treat drug addiction e.g., naltrexone and buprenorphine,
- medicines to treat epilepsy (e.g., phenytoin, phenobarbital and carbamazepine),
- vitamin tablets (containing C-vitamin),
- medicines to treat diarrhoea (loperamide, diphenoxylate),
- medicines and products that make the urine more acidic such as ammonium chloride (sal ammoniac),
- diuretic medicines (spironolactone),
- medicines that make you sleepy or drowsy,
- herbal medicines containing St John's wort.

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

You must tell your doctor about all other medicines that you are taking, since they may potentially

be dangerous if they are taken with methadone. In such situations your doctor may decide that your heart should be monitored with ECG in the beginning of the treatment to check that no such effects occur. Methadone may also affect certain blood- and urine samples. Tell your doctor that you take methadone before any test is performed.

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)

{Invented name} with drink and alcohol

You are not allowed to drink alcohol while taking {Invented name} since this can give serious side effects. Do not drink grapefruit juice while being treated with {Invented name}, since this may change the effect of the medicine.

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 or pharmacist for advice before taking this medicine.

It is recommended not to use {Invented name} during labor. Do not use {Invented name} if you are pregnant unless you have been told to do so 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.

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 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.

{Invented name} contains 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 {Invented name}

Always take this medicine exactly as your doctor 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 {Invented name}, 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 {Invented name}).

It is important that you do not take more than the dose that you and your doctor have agreed upon. The

individual need may be different. Modification or discontinuation of treatment should only be done in consultation with your doctor.

This product is for oral use only, and must not be injected.

{Invented name} 5 mg tablets: The tablet can be divided into equal doses.

{Invented name} 10 mg tablets: The score line is only there to help you break the tablet if you have difficulty swallowing it whole but not to divide into equal doses.

Drug addiction

Adults: The doctor will adjust the dosage according to your needs.

The usual initial dose is 10-30 mg. In patients with high opioid tolerance the initial dose is 25-40 mg. The dose is then increased gradually over a period of 3 weeks.

The usual maintenance dose is 60-120 mg daily, but some patients need higher doses.

The maximum daily dose for treatment of drug addiction should not exceed 150 mg.

Severe pain

Adults: The usual initial dose is 5 mg 1-3 times/daily. Thereafter the dose can be increased slowly. Patients who have taken opioids earlier may start the treatment at higher doses, 5-20 mg 2-3 times/daily, since their earlier experience of opioid treatment is taken into consideration.

Continued determination of the daily dose, the dividing of doses and all dose adjustments during the treatment are done by the attending doctor and depends on the previous dose.

Elderly:

It may be necessary to decrease the initial dose and you may need more close follow up when you are taking {Invented name}. Follow the doctor's advice.

Impaired liver or kidney function:

It may be necessary to decrease the dose or extend the dosage interval. Follow the doctor's advice.

If you take more {Invented name} 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 immediate medical care.

Signs of overdose of {Invented name} may be:

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

Contact your doctor if any of the above symptoms occur. Children and elderly are more sensitive to this medicine.

If you forget to take {Invented name}

Do not take a double dose to make up for a forgotten tablet.

If you stop taking {Invented name}

You should only discontinue or terminate the treatment after talking with your doctor. You should not suddenly discontinue taking {Invented name}, since you may experience withdrawal symptoms such as sleeplessness, running nose, tearing, anorexia, diarrhoea and pains.

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):

- Nausea or vomiting

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

- Weight increase
- accumulation of water in the body
- constipation
- excitement (euphoria), you see or hear things that are not real (hallucinations)
- a feeling of dizziness or that you are spinning around
- blurred vision, pinpoint pupils
- drowsiness
- rash, sweating
- tiredness

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

- Loss of appetite
- breathing difficulties (with cough)
- mouth dryness, inflammation in the tongue
- depressed mood (dysphoria), anxiety, sleep disturbance, confusion, decreased sexual drive
- headache, fainting
- itching, urticaria, rash
- swollen legs, weakness, accumulation of water in the body
- seizure in the bile ducts (gives stomach ache)
- facial flush, low blood pressure
- difficulties to pass water
- difficulties in achieving or maintaining erection, menstrual disorders

Rare side effects (may affect up to 1 in 1,000 people):

- Heart disorders, slower pulse, palpitation

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

- too low level of potassium or magnesium in the blood, low blood sugar
- decreased number of blood platelets in the blood
- you can become dependent on {Invented name}
(for more information see section 2, Warnings and Precautions)
- mood change
- sleep apnoea (breathing pauses during sleep)
- heart attack, abnormal heart rhythm
- sudden fall in blood pressure on standing that can cause dizziness or fainting
- sudden death, hypothermia (a dangerously low body temperature)
- 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 {Invented name}

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 store above 30 °C.

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

Do not throw 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 {Invented name} contains

- The active substance is methadone hydrochloride.
- The other ingredients are lactose monohydrate, pregelatinised maize starch and magnesium stearate.

What {Invented name} looks like and contents of the pack

{Invented name} 5 mg tablets are white to almost white, round and flat tablets with the marking '5' on one side and score line on the other side (see section 3 "How to take {Invented name}").

{Invented name} 10 mg tablets are white to almost white, round and flat tablets with the marking '10' on one side and score line on the other side (see section 3 "How to take {Invented name}").

{Invented name} is packed in Al/PVC/PVDC blisters or white HDPE bottles with child-resistant closure.

Pack-sizes:

10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 and 100 tablets in blisters.

25, 100 and 200 tablets in bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden:	Metadon 2care4, 5 mg / 10 mg tablett
Denmark:	Metadon 2care4, tabletter 5 mg / 10 mg
Iceland:	Metadon 2care4 5 mg / 10 mg tafla

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