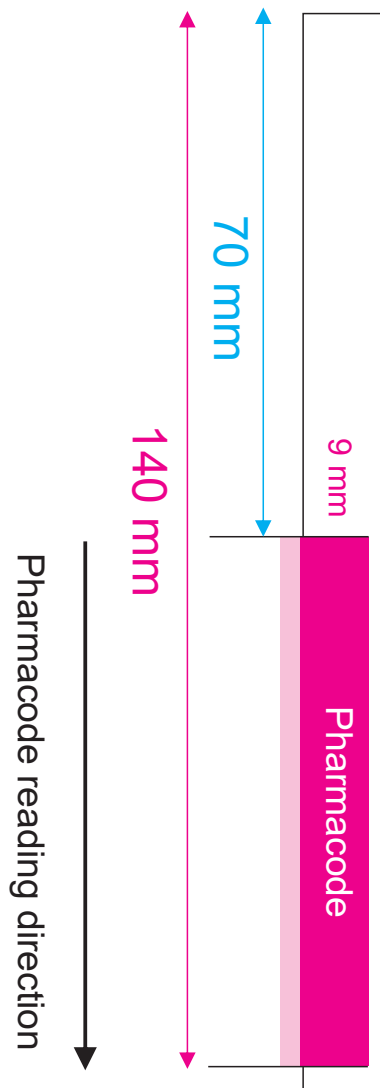
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Package Leaflet: Information for the patient

Methadone Hydrochloride 5 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, 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 Hydrochloride 5 mg tablets (hereinafter: Methadone Hydrochloride) is and what it is used for
2. What you need to know before you take Methadone Hydrochloride
3. How to take Methadone Hydrochloride
4. Possible side effects
5. How to store Methadone Hydrochloride
6. Contents of the pack and other information

1. What Methadone Hydrochloride is and what it is used for

The active ingredient of this medicine, Methadone Hydrochloride 5 mg tablets, is a synthetic opiate (a morphine-like drug) used in the treatment of moderate to severe pain.
You must talk to a doctor if you do not feel better or if you feel worse.

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

Do not take Methadone Hydrochloride if:
- You are allergic to methadone or any of the other 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 Hydrochloride is not suitable for children.
Warnings and precautions
Talk to your doctor or pharmacist before taking Methadone Hydrochloride 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.
- Pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

You should be aware that prolonged use of methadone can result in tolerance of the drug and both physical and psychological addiction to methadone. If you have any concerns speak to your doctor before you are given this 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.

Methadone Hydrochloride 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.

Other medicines and Methadone Hydrochloride
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, itranozole, 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. (antipsychotics) 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.

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.

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

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

Pregnancy
If used during pregnancy, your baby may suffer from withdrawal syndromes. Take care if you are taking a pregnancy test as methadone may interfere with the results.
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.

Breast-feeding
If you breast-feed whilst taking this medicine, small amounts can pass to the baby in the breast milk.

Labour:
You should not take Methadone Hydrochloride 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.

Methadone Hydrochloride contains lactose monohydrate
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 Hydrochloride

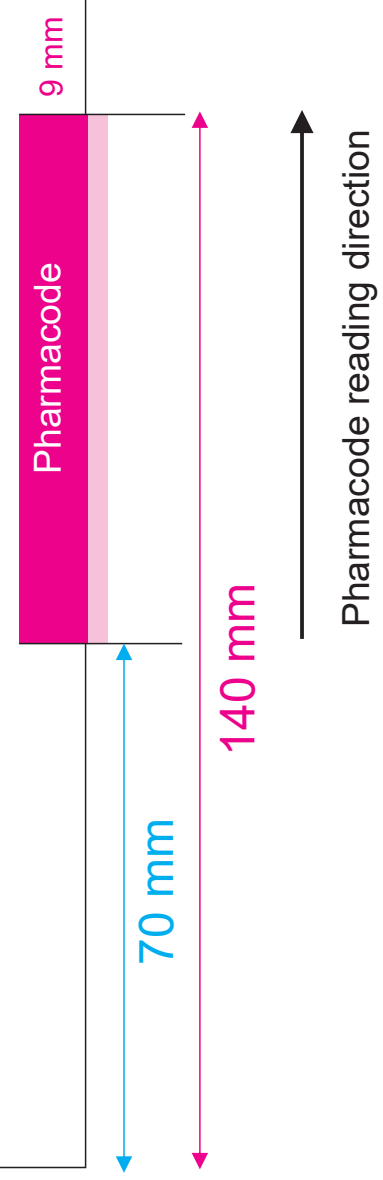
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important that you do not take more than the dose agreed with your doctor. You can become dependent on Methadone Hydrochloride.

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.

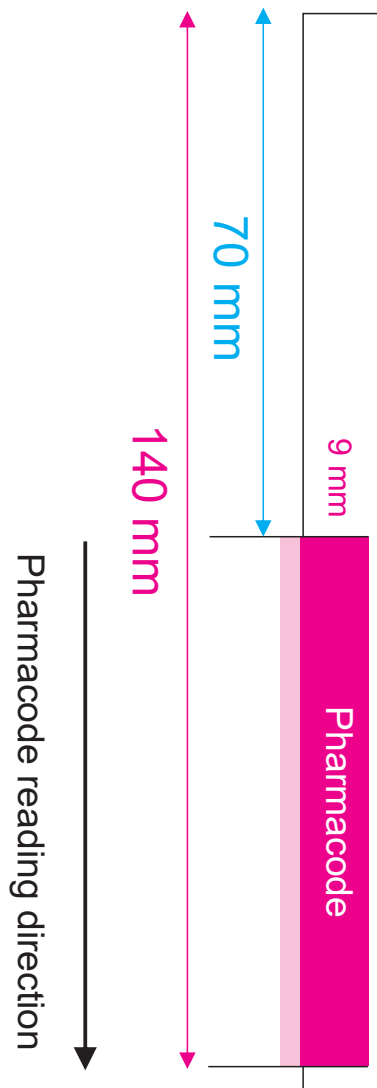
Elderly or ill:
If you are elderly or ill, your doctor will only prescribe repeated doses with caution.

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

If you forget to take Methadone Hydrochloride
During a course of treatment, it is important that, should you miss a dose, you take the dose as soon as you remember.



210 mm x 450 mm leaflet pharmacode placement



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 Hydrochloride
Do not stop taking your medicine except on medical advice.

If you take more Methadone Hydrochloride than you should
If you take too many Methadone Hydrochloride, 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.

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

The product is for oral use and must not be injected.

There is a risk that you may become addicted to or dependent on these tablets (a need to keep taking the medicines). If you take these for a long time you can become used to the effects and you may need to take higher doses to control your pain.

You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking you tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects.

If you suddenly stop taking these tablets you may get withdrawal symptoms such as
- agitation,
- anxiety,
- palpitations
- shaking or
- sweating

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Repeated use of methadone 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 is 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)

Common (may affect up to 1 in 10 people):
- 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.
- 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 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 Hydrochloride

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
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 Methadone Hydrochloride contains
- The **active ingredient** is Methadone Hydrochloride 5mg per tablet.
- The **other ingredients** are lactose monohydrate, maize starch, povidone K25, silica colloidal anhydrous, talc, magnesium stearate.

What Methadone Hydrochloride looks like and contents of the pack
White or almost white, round, flat uncoated tablets of 7 mm, imprinted with “M5” on one side and concave with a score line on the other side. The score line is not intended for breaking the tablet.

28, 30 or 50 tablets in clear, colourless PVC/PVDC//Al blisters in a carton box with leaflet.

Not all pack sizes may be marketed.

Marketing authorisation holder
Ascot Laboratories Limited;
Ascot House 1, Warwick place,
Warwick road, Borehamwood
WD6 1UA
United Kingdom

Manufacturer
ExtractumPharma Zrt.
Head office: H-1044 Budapest, Megyeri út 64., Hungary
Site of manufacture: H-6413 Kunfehértó, IV. körzet 6, Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:
Methadone Hydrochloride 5 mg tablets

This leaflet was last revised in May 2026.

