

PACKAGE LEAFLET: INFORMATION FOR THE USER

Methadone Mixture DTF 1mg/1ml

Methadone Hydrochloride

(This medicine will be referred to as Methadone Mixture in this leaflet)

Read all of this leaflet carefully before you take Methadone Mixture 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Methadone Mixture is and what it is used for
2. What you need to know before you take Methadone Mixture
3. How to take Methadone Mixture
4. Possible side effects
5. How to store Methadone Mixture
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 Mixture is and what it is used for

This medicine has been prescribed for you for the treatment of addiction in order to reduce withdrawal symptoms. It contains the methadone which belongs to a class of medicines called opioids.

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. 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.

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

Do not take Methadone Mixture 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 have a bowel disorder known as paralytic ileus
- 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 are a child.
- You are dependent on other non-opioid drugs.
- You have phaeochromocytoma, a tumour of the adrenal glands

Warnings and precautions

Talk to your doctor or pharmacist before taking Methadone Mixture 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.

- You have a condition that causes severe muscle weakness and fatigue (myasthenia gravis).
- You are in shock.
- You are taking medicines called CNS depressants to treat anxiety, acute stress and panic attacks.

Taking this medicine regularly, particularly for a long time, can lead to addiction

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).

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

- 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.

During treatment, this medicine should not be stopped suddenly, but gradually, as sudden stoppage could lead to withdrawal symptoms.

Methadone Mixture 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 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 Mixture

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 and buprenorphine
- cimetidine (a medicine used to treat stomach ulcers)
- drugs used to treat epilepsy (e.g. phenytoin, phenobarbital, primidone and carbamazepine)
- naloxone (a medicine used to treat difficulties with breathing)
- antibiotics (medicines used to treat bacterial infections)
- antifungals (medicines used to treat fungal infections)
- medicines that make urine more acidic e.g. ammonium chloride
- antiviral drugs including some medicines used to treat HIV e.g. nevirapine, zidovudine, efavirenz, nelfinavir, ritonavir and abacavir
- metoclopramide or domperidone (medicines used to stop you feeling and being sick)
- mexiletine (a drug used to treat heart irregularities)
- medicines used to treat depression including fluvoxamine, tricyclic antidepressants such as amitriptyline and imipramine, 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)
- other opioid type drugs e.g. morphine

- pentazocine (a pain killer)
- medicines used to help you relax (tranquillisers)
- medicines used to help you to sleep (sedatives).
- herbal medicines including St John's Wort
- medicines used to treat tuberculosis (rifampicin)
- Medicines used to treat certain mental and emotional conditions (anti-psychotics)
- Medicines used to treat pain and fever such as metamizole.

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. 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 Mixture 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 Mixture together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. 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 Mixture with food, drink and alcohol

You must not drink alcohol whilst you are taking Methadone Mixture as this could cause serious side effects.

You are advised not to drink grapefruit juice whilst you are being treated with Methadone Mixture 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. 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.

Pregnancy:

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

Breast-feeding:

Do not take Methadone Mixture while you are breastfeeding as methadone passes into breast milk and will affect your baby.

Labour:

You should not take Methadone Mixture 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.

This 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 Mixture contains:

- glycerol which may cause headache, stomach upset and diarrhoea
- Tartrazine (E102) and sunset yellow (E110) which may cause allergic reactions.
- 26.49g of demineralised liquid sucrose per maximum daily dose. This should be taken into account if you suffer from diabetes mellitus. It may also be harmful to your teeth.

3. How to take Methadone Mixture

You must only take Methadone Mixture by mouth. Under no circumstances should you inject this product as injection may cause serious and permanent damage to your body with possibly fatal consequences.

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 Mixture. Your prescriber should discuss your treatment and whether you need to continue taking Methadone Mixture at regular intervals. If you and your prescriber decide to stop treatment a plan will be put in place to gradually reduce the dose and stop taking the medicine to minimise the risk of withdrawal effects.

Adults:

For the treatment of drug addiction:

The recommended initial dose is 10-20 mg a day. The dose will be slowly increased until you show no signs of withdrawal or intoxication. The usual dose is 40-60mg/day. Your doctor will decide what dose you need and when to reduce the dose.

Elderly or ill:

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

Children:

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 Mixture

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.

If you stop taking Methadone Mixture

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.

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

If you take more Methadone Mixture than you should

If you take too much Methadone Mixture, you can experience the following:

- difficulty in breathing
- extreme sleepiness, fainting or coma
- pin point pupils
- muscle weakness
- cold and clammy skin
- low blood sugar
- slow heartbeat, low blood pressure, heart attack or shock. In severe cases death may occur.

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

Continued overleaf

methadone poisoning.

4. Possible side effects

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

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

Stop taking this medicine and see a doctor straightaway if you have any of the following:

- If you have asthma and it gets worse
- 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

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):

- changes in your mood, feeling 'high' or over excited
- seeing or hearing things that are not there (hallucinations)
- drowsiness or sleepiness (sedation)
- blurred vision
- dry eyes
- small pupils
- dizziness, spinning sensation
- constipation
- rash
- sweating
- tiredness
- drowsiness
- weight increase

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

- feeling tense and restless
- addiction to this medicine
- 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 nose
- 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
- low body heat(hypothermia)
- unusual weakness (asthenia)
- disorder of the biliary part of the digestive system (bile duct dyskinesia)

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

- High prolactin levels in the blood
- Rapid, uncontrollable movements of the eyes
- dependence and addiction
- low blood sugar

Drug Withdrawal

When you stop taking Methadone Mixture, 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.

You may notice that some of the side effects become less severe with time as you get used to this medicine.

When taken for a long period of time, it is possible that you may become dependent on Methadone Mixture.

This product contains sunset yellow which may cause allergic reaction.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist nurse. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via 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 Mixture

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 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. Store below 25°C and protect from light.

6. Contents of the pack and other information

What Methadone Mixture contains

The **active ingredient** is Methadone Hydrochloride 1mg in 1ml. The **other ingredients** are demineralised liquid sucrose, glycerol (E422), hydrochloric acid (E507), sodium hydroxide (for pH adjustment), sodium benzoate (E211), purified water and colours tartrazine (E102), sunset yellow (E110), green S (E142).

What Methadone Mixture looks like and the contents of the pack

Methadone Mixture is a bright green liquid, supplied in amber glass bottles, each containing 500, 100, 50 or 30ml of the liquid, or it is supplied in HDPE plastic bottles, each containing 5l, 2.5l, 1l or 500ml of the liquid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Macarthy's Laboratories Ltd T/A Martindale Pharma,
Bampton Road, Harold Hill, Romford, Essex,
RM3 8UG, United Kingdom

Manufacturers:

Macarthy's Laboratories Limited T/A Martindale Pharma,
Bampton Road, Romford, Essex, RM3 8UG, United Kingdom

Or

Dales Pharmaceuticals Limited,
Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire
BD23 2RW, United Kingdom

If this leaflet is difficult to see or read, please contact the marketing authorisation holder for help.

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 **MARTINDALE PHARMA**
Bampton Road, Harold Hill, Romford, RM3 8UG, UK