

PACKAGE LEAFLET: INFORMATION FOR THE USER  
**Methadone Mixture DTF (Sugar Free) 1mg in 1ml Oral Solution**  
Methadone Hydrochloride

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

**Read all 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, please ask your doctor or pharmacist
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

**What is in this leaflet:**

1. What Methadone Mixture (Sugar Free) is and what it is used for
2. What you need to know before you take Methadone Mixture (Sugar Free)
3. How to take Methadone Mixture (Sugar Free)
4. Possible side effects
5. How to store Methadone Mixture (Sugar Free)
6. Contents of the pack and other information

**1. What Methadone Mixture (Sugar Free) is and what it is used for**

Methadone is a synthetic opiate (a morphine-like drug) used in the treatment of addiction in order to reduce withdrawal symptoms.

**2. What you need to know before you take Methadone Mixture (Sugar Free)**

**Do not take Methadone Mixture (Sugar Free) 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 taking central nervous systems (CNS) depressants (medicines that dull the senses including tranquillisers, sedatives and antidepressants)
- You are in labour.
- You have a bowel problem called ulcerative colitis.
- You are dependent on other non-opioid drugs.
- You have severe liver disease.
- You suffer from sudden involuntary muscle contraction of the bile ducts and kidney.

**Children and adolescents**

Methadone Mixture (Sugar Free) is not suitable for children

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Methadone Mixture (Sugar Free) 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 or constipation.
- 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.

If any of the conditions above apply to you, please consult your doctor.

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

- 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.

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).

Methadone 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.

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

### **Other medicines and Methadone Mixture (Sugar Free)**

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

Tell your doctor if you are taking any of the following:

- medicines used to treat addiction e.g. naltrexone and buprenorphine
- cimetidine (a medicine used to treat stomach ulcers)

- naloxone (a medicine used to treat an overdose of opioid medicines).
- antibiotics (medicines used to treat bacterial infections) e.g. ciprofloxacin.
- antifungals (medicines used to treat fungal infections).
- medicines that make urine more acidic e.g. ammonium chloride.
- antiviral medicines including some medicines used to treat HIV e.g. nevirapine, zidovudine, efavirenz, nelfinavir and ritonavir.
- Medicines used to treat depression including fluvoxamine and fluoxetine, tricyclic antidepressants such as amitriptyline and imipramine
- CNS depressants (medicines that act on the brain and cause drowsiness or sleepiness).
- a type of medicine called Monoamine Oxidase Inhibitors (MAOIs) ,including moclobemide which are used to treat depression, within the past 2 weeks.
- 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 irregular heartbeat (arrhythmia) such as amiodarone, diltiazem, disopyramide, procainamide, sotalol and verapamil.
- medicines which affect electrolyte balance such as laxatives, diuretics (water tablets) or lithium.
- serotonergic medicines used to treat migraine, such as sumatriptan.
- serotonergic anti-emetics medicines used to treat nausea and vomiting, such as ondansetron.
- medicines known as neuromuscular blocking agents, usually used when you are having an operation.
- medicines used to treat epilepsy such as phenytoin, phenobarbital, carbamazepine and primidone.

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.

### **Taking Methadone Mixture (Sugar Free) with alcohol**

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

### **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**

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.

**Breast-feeding:**

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

**Labour:**

You should not take this medicine 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.

**Important information about some of the ingredients**

Methadone Mixture (Sugar Free) contains:

- Colouring agent Sunset Yellow (E110) which may cause an allergic reaction
- Liquid maltitol. If you have been told by your doctor you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 1.2 mg sodium benzoate in each ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Less than 1 mmol sodium (23 mg) per daily dose, that is to say essentially 'sodium-free'.

**3. How to take Methadone Mixture (Sugar Free)**

You must only take Methadone Mixture (Sugar Free) 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.

Your doctor will tell you how much Methadone Mixture (Sugar Free) 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. You can become dependant on Methadone Mixture (Sugar Free).

**Adults:**

The usual initial dose is 10-20mg a day. The dose will be slowly increased until you show no signs of withdrawal or intoxication, usually up to around 40 - 60mg a 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.

**Use in 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 (Sugar Free)**

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 Mixture (Sugar Free) Do not stop taking your medicine except on medical advice, because your withdrawal symptoms may come back.

**If you take more Methadone Mixture (Sugar Free) than you should**

If you take too much Methadone Mixture (Sugar Free), you can experience the following:

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

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, Methadone Mixture (Sugar Free) can cause side effects, though not everybody gets them.

**Tolerance, addiction and withdrawal****Repeated use of methadone can result in tolerance and addiction.**

Prolonged use of this medicine can result in mental and physical dependence on methadone which may result in withdrawal symptoms if your treatment is stopped too quickly. The withdrawal symptoms of Methadone Mixture Sugar Free include sweating, anxiety, difficulty sleeping, loss of appetite, pain, stomach cramps and diarrhoea. If you are worried about this possible side effect please talk to your doctor. If any of the following symptoms occur tell your doctor or nurse immediately. These are symptoms of a serious allergic reaction.

- sudden wheeziness and tightness of chest
- swelling of eyelids, face or lips
- skin lumps or hives
- skin rash (red spots), itchiness, fever
- collapse

Keep taking the medicine but tell your doctor straight away if you get any of the following side effects:

- 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.

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

- heart problems. The signs of this may include changes in the way your heart beats, such as it beating faster or slower or missed heart beats, breathing difficulties and dizziness
- if your breathing becomes slow and shallow.

Tell your doctor if you get any of these side effects:

- feeling sick (nausea) or being sick (vomiting)
- constipation
- sweating a lot more than usual
- feeling dizzy, particularly when standing up. This may be a sign that you have low blood pressure
- small pupils
- breast growth and production of breast milk
- difficulty in passing water (urine), pain in the lower back and abdomen caused by muscle spasms
- dry mouth, eyes or nose, facial flushing
- feeling drowsy, confused or restless
- changes in your mood, feeling “high” or over excited
- seeing or hearing things that are not there (hallucinations)
- headache, rashes
- low body heat (hypothermia)
- lower sexual urge or desire
- painful periods or lack of periods.
- low blood sugar (frequency not known)

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

When taken for a long period of time, it is possible that you may become dependent on Methadone Mixture (Sugar Free). This product contains sunset yellow which may cause allergic reaction.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

If any of the side effects get serious or you notice side effects not listed in this leaflet please contact your doctor or pharmacist.

### **5. How to store Methadone Mixture (Sugar Free)**

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.

Once you have opened the bottle you are advised to dispose of it after 4 weeks.

Do not store above 25°C.

## **6. Contents of the pack and other information**

### **What Methadone Mixture (Sugar Free) contains:**

The active ingredient is Methadone Hydrochloride 1mg in 1ml.

The other ingredients are Liquid maltitol, sodium benzoate, purified water and colours E110 (sunset yellow FCF), E142 (green S) and E104 (quinoline yellow).

### **What Methadone Mixture (Sugar Free) looks like and the contents of the pack:**

Methadone Mixture (Sugar Free) is a bright green liquid, supplied in amber glass bottles which contain 500ml, 100ml, 50ml or 30ml of the solution.

**Marketing Authorisation Holder:** Ethypharm 194, Bureaux de la Colline, Bâtiment D 92213, Saint-Cloud Cedex, France

**Manufacturer:** Martindale Pharmaceuticals, Bampton Road, Harold Hill, Essex RM3 8UG, UK

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