

Consumer Medicine Information

# Methadone Molteni

## *Methadone hydrochloride*

Oral solution 1 mg/mL, 5 mg/mL, 10 mg/mL

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## What is in this leaflet

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Please read this leaflet carefully before you start taking Methadone Molteni.

This leaflet answers some common questions about Methadone Molteni. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from [www.medsafe.govt.nz](http://www.medsafe.govt.nz).

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Methadone Molteni against the benefits this medicine is expected to have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may want to read it again.

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## What Methadone Molteni is used for

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Methadone Molteni is a medicine to be taken by mouth to suppress the craving for opiate-type drugs in people who are addicted to them. Methadone, the active ingredient, is a synthetic opiate similar to morphine because it acts on the central nervous system to suppress withdrawal symptoms.

Methadone Molteni must not be used for indications other than suppression of opioid withdrawal symptoms unless approved by your doctor.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

Methadone Molteni is only available on prescription from doctors authorised to prescribe Controlled Drugs for the treatment of opioid dependence.

Methadone Molteni is itself addictive.

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## Before you take Methadone Molteni

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Methadone Molteni is not suitable for everyone.

### ***When you must not take it***

#### **Do not take Methadone Molteni if:**

- you are allergic to methadone or any of the ingredients listed at the end of this leaflet
- your breathing is shallow, especially in the presence of cyanosis (blue coloured skin) or excessive lung secretions
- you are having an attack of asthma
- you have acute alcoholism, a head injury or raised blood pressure in the head
- you are taking a certain type of antidepressants known as monoamine oxidase inhibitors (MAOIs)
- you have ulcerative colitis
- you have severe liver or kidney disease.

The presence of the above conditions may mean that you cannot take methadone or that your dose level may need to be modified. Your doctor will advise you.

#### **Do not take it after the expiry date ('EXP') printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

#### **Do not take it if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you should start using this medicine, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- problems with your central nervous system function or acute stomach conditions. Methadone may interfere with the diagnosis of these conditions.
- low blood pressure (feeling faint or dizzy). You may be more sensitive to these effects while taking methadone.
- difficulty passing urine
- decreased sexual drive
- liver or kidney problems, especially if you are elderly. Careful monitoring of patients with these conditions is advised because methadone may build up in the system.

**Also tell your doctor if:**

- you are taking medicine to control your heart rhythm.
- you are or become pregnant while taking Methadone Molteni. The main risks to mother and baby relate to changing methadone levels, particularly if this leads to withdrawal symptoms. Your healthcare professional will provide you with information relating to the effect of methadone maintenance therapy, smoking, alcohol and illicit drug use on your baby.
- you are breast-feeding or intending to breast-feed. Methadone passes into breast milk and may cause side effects in your baby. However, your doctor will assess the risks against the benefits of breast-feeding before prescribing Methadone Molteni. When you decide to wean your baby you should do so slowly to avoid a sudden change in baby's methadone level.

***Taking other medicines***

**Tell your doctor or pharmacist if you taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

**Tell any healthcare professional who is prescribing a new medicine for you that you are taking Methadone Molteni.**

Your doctor or pharmacist has a complete list of medicines that may interfere with methadone.

Some of the more important medicines that may interact with methadone are listed below.

Alcohol, benzodiazepines, buprenorphine, carbamazepine, chloromethiazole, cyclizine and other non-sedating antihistamines, desipramine, fluoxetine, fluvoxamine, indinavir, ketoconazole, naltrexone, naloxone, nevarapine, phenobarbitone, phenytoin, rifampicin, ritonavir, urine acidifiers such as ascorbic acid (vitamin C), urine alkalinisers such as sodium bicarbonate, zidovudine, zopiclone, other opioid drugs and other drugs that depress the central nervous system.

**Tell your doctor or pharmacist before taking any of the above medicines.**

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## **How to take Methadone Molteni**

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Methadone Molteni is intended to be taken only by mouth. The dose varies very widely for different individuals. It is very important that you take your Methadone Molteni, including takeaway doses, exactly as prescribed and at the time advised, to keep your blood levels stable.

**Do not give your Methadone Molteni dose to anyone else.**

**Do not stop taking Methadone Molteni or change your dosage unless you have first discussed this with your doctor.**

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## While you are taking Methadone Molteni

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### *Things to be careful of*

**Be careful driving, operating machinery or doing work that requires you to be alert after you have a dose of methadone until you know how it affects you.**

If you are well stabilised on Methadone Molteni, you may continue to drive and operate machinery as part of normal activities. If your Methadone Molteni dosage has not been stabilised or is changed for any reason you need to be careful because drowsiness may be increased and there may be other side effects while you get used to the new dose.

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## In case of overdose

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**Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Methadone Molteni.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Methadone Molteni.**

Like all medicines, Methadone Molteni may occasionally cause side effects in some people. Sometimes they are serious and require medical treatment, but mostly they require some change to the dosage level.

**Ask your doctor or pharmacist to answer any questions you may have.**

The most common side effects with methadone are nausea, vomiting, constipation, drowsiness and confusion.

Other side effects include sweating, facial flushing, dizziness, irregular heartbeat, palpitations, fall in blood pressure on standing, low body temperature, restlessness and contraction of the pupils. Itching, rash and contact dermatitis may also occur.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some patients.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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## After taking Methadone Molteni

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### ***Storage***

Store takeaway doses of Methadone Molteni in a cool dry place where the temperature stays below 25°C, protected from light. Do not refrigerate.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Methadone Molteni past its expiry date.

Never leave Methadone Molteni lying around.

### ***Disposal***

Return any unused medicine, and any medicine past its expiry date (as shown on the labelling), to your pharmacy.

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## Product description

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### ***What it looks like***

Methadone Molteni products present as clear, syrupy liquid with cherry taste.

The 1 mg/mL strength is coloured green, the 5 mg/mL strength is light amber and the 10 mg/mL strength is blue. They are available in 100 mL amber plastic bottles with a child resistance cap. Measuring devices are included.

### ***Ingredients***

#### Active ingredient:

- methadone hydrochloride

#### Inactive ingredients:

- xylitol
- glycerol
- sodium benzoate
- citric acid monohydrate
- cherry flavour
- hydroxyethylcellulose

- purified water
- colouring agent(s)
  - 1 mg/mL: Brilliant blue FCF (E133), Tartrazine (E102)
  - 5 mg/mL: Caramel – Ammonia (E150C)
  - 10 mg/mL: Brilliant blue FCF (E133)

Methadone Molteni does not contain lactose and is sugar-free. The 1 mg/mL oral solution contains tartrazine as a colouring agent, which may cause allergic reactions.

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## **Sponsor details**

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BNM Group  
39 Anzac Road  
Browns Bay  
Auckland 0753

Ph: 0800 565 633

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## **Date of preparation**

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This leaflet was prepared on 17 October 2013.