

Methadone-AFT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Methadone-AFT?

Methadone-AFT contains the active ingredient methadone. Methadone-AFT is used for the relief of chronic, moderate to severe pain.

For more information, see Section [1. Why am I using Methadone-AFT?](#) in the full CMI.

2. What should I know before I use Methadone-AFT?

Do not use if you have ever had an allergic reaction to methadone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Methadone-AFT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Methadone-AFT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Methadone-AFT?

- The usual dose for adults is one tablet (5 mg or 10 mg) taken 2 to 3 times a day, but this dosage may be adjusted by your doctor.
- Methadone-AFT tablets are not recommended for use in children. The doctor may prescribe a smaller dose in elderly patients.

More instructions can be found in Section [4. How do I use Methadone-AFT?](#) in the full CMI.

5. What should I know while using Methadone-AFT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Methadone-AFT.• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not use Methadone-AFT to treat any other complaints unless your doctor says to.
Driving or using machines	Methadone-AFT tablets may cause drowsiness. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• You must not drink alcohol while taking Methadone-AFT tablets.
Looking after your medicine	Keep Methadone-AFT tablets in a cool, dry place, where the temperature stays below 25 °C. Keep Methadone-AFT tablets where children cannot reach them.

For more information, see Section [5. What should I know while using Methadone-AFT?](#) in the full CMI.

6. Are there any side effects?

Common and less serious side effects of Methadone-AFT include nausea, vomiting, constipation, dizziness, confusion, dry mouth, sweating and problems with urine flow. Serious side effects include difficulty in breathing, hayfever, hives, fainting and swelling in lips/ mouth.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING

Limitations of use

Methadone-AFT tablets should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Methadone-AFT tablets poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Methadone-AFT tablets can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Methadone-AFT tablets and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while taking Methadone-AFT tablets

Taking Methadone-AFT tablets with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentin, pregabalin, cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while taking Methadone-AFT tablets.

Methadone-AFT

Active ingredient: Methadone hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Methadone-AFT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Methadone-AFT.**

Where to find information in this leaflet:

- [1. Why am I using Methadone-AFT?](#)
- [2. What should I know before I use Methadone-AFT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Methadone-AFT?](#)
- [5. What should I know while using Methadone-AFT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Methadone-AFT?

Methadone-AFT contains the active ingredient methadone hydrochloride which belongs to a group of medicines called opioid analgesics.

Methadone-AFT is used for the relief of chronic, moderate to severe pain.

2. What should I know before I use Methadone-AFT?

Warnings

Addiction

You can become addicted to Methadone-AFT tablets even if you take it exactly as prescribed. Methadone-AFT tablets may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking this medicine. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Methadone-AFT tablets suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Methadone-AFT tablets may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you.

If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating

Methadone-AFT tablets given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Ask your doctor if you have any questions about why Methadone-AFT has been prescribed for you.

Your doctor may have prescribed it for another reason.

Do not use Methadone-AFT if:

- you have ever had an allergic reaction to methadone hydrochloride (the active ingredient in Methadone-AFT tablets); any other opioid drug; or any of the ingredients listed at the end of this leaflet.
- you have any other medical condition including:
 - suffering from a lung disorder such as asthma, or any illness causing difficulty in breathing, especially if there is excessive phlegm or skin is bluish in colour
 - a recent head injury, or increased pressure in the head
 - a bowel condition known as ulcerative colitis
 - certain liver or kidney conditions
 - certain heart conditions
 - alcoholism.
- you are taking or have recently taken antidepressants of the type called monoamine oxidase inhibitors (MAOIs)
- you suffer from biliary and renal tract spasm
- the expiry date (EXP) printed on the pack has passed
- the packaging is torn or shows signs of tampering

Check with your doctor if you:

- you are allergic to foods, dyes, preservatives or any other medicines
- you are pregnant, or become pregnant while taking Methadone-AFT, are about to give birth, or are breastfeeding
- you have any other medical condition including:
 - hormone problems
 - diabetes
 - prostate disease
 - pheochromocytoma (a rare tumour of the adrenal gland). Symptoms include bouts of anxiety and headaches. There may be palpitations (banging of the heart felt in the chest), dizziness, weakness, nausea, vomiting, diarrhoea, dilated pupils, blurry vision, stomach pains and raised blood pressure.
- you intend to drink alcohol while taking Methadone-AFT.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with Methadone-AFT and affect how it works.

Extreme caution is necessary if Methadone-AFT is prescribed with any drug known to have the potential to prolong the QT interval. Interactions may occur with methadone and potentially arrhythmogenic agents such as class I and III antiarrhythmics, some neuroleptics and tricyclic antidepressants, and calcium channel blockers.

Caution should also be exercised when prescribing concomitant drugs capable of inducing electrolyte disturbances that may prolong the QT interval (hypomagnesaemia, hypokalaemia). These include diuretics, laxatives and in rare cases mineralocorticoid hormones.

Medicines that may increase the metabolism of methadone include rifampicin, phenytoin, carbamazepine, St John's Wort, and antiretroviral agents used in the treatment of HIV infection (particularly nevirapine, efavirenz and some protease inhibitors). **This has the potential to result in withdrawal symptoms.**

Patients who are also taking enzyme inducers such as carbamazepine, may require higher than typical doses of methadone.

Some compounds may decrease the metabolism of methadone e.g. fluconazole and some selective serotonin re-uptake inhibitors (SSRIs), particularly fluvoxamine. **This may increase the likelihood of methadone toxicity.**

Methadone can also affect the metabolism of other drugs. Plasma concentrations of some drugs may be increased, e.g. nelfinavir, zidovudine, fluconazole and desipramine, whereas concentrations of others may be decreased, e.g. abacavir and amprenavir.

Monoamine oxidase inhibitors (MAOIs) may prolong and enhance the respiratory depressant effects of methadone. **Opioids and MAOIs used together may cause fatal hypotension and coma.**

The general depressant effects of methadone may be enhanced by other centrally-acting agents such as other opioids, alcohol, antihistamines, antipsychotics, barbiturates, benzodiazepines, cannabis, centrally-acting

anti-emetics, gabapentinoids, hypnotics, neuromuscular blocking agents, phenothiazines, sedatives, tricyclic antidepressants, tranquillisers and other CNS depressants

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Methadone-AFT.

4. How do I use Methadone-AFT?

How much to take

- The usual dose for adults is one tablet (5 mg or 10 mg) taken 2 to 3 times a day, but this dosage may be adjusted by your doctor.
- Methadone-AFT tablets are not recommended for use in children. The doctor may prescribe a smaller dose in elderly patients.
- **Follow all the instructions provided to you by your doctor and pharmacist. Do not take more than the recommended dose. Do not stop taking Methadone-AFT or change the dose without first checking with your doctor.**

How to take it

Swallow the tablet with a glass of water

If you forget to take Methadone-AFT

Methadone-AFT should be used as instructed by your doctor or pharmacist. If you forget to take a dose, take it as soon as you remember and then go on as before, but remember not to take the tablets more often than recommended by your doctor.

If you use too much Methadone-AFT

If you think that you have used too much Methadone-AFT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you or someone else receive too much (overdose) and experience one or more of the symptoms below, immediately call for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally taken Methadone-AFT tablets that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits

When seeking medical attention, take this information and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which you have been taken.

5. What should I know while using Methadone-AFT?

Things you should do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Seek medical help immediately if Methadone-AFT is accidentally taken by a child.

Things you should not do

- Do not stop using this medicine without first checking with your doctor.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use Methadone-AFT to treat any other complaints unless your doctor says so

Things to be careful of

Particular care should be taken when starting treatment with Methadone-AFT or increasing the dose. The medicine can decrease heart and breathing rates, which if severe may lead to death.

Speak to your doctor immediately if you have any concerns.

Driving or using machines

Methadone-AFT tablets may cause drowsiness. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required.

Drinking alcohol

Tell your doctor if you drink alcohol.

You must not drink alcohol while taking Methadone-AFT tablets.

Looking after your medicine

Keep Methadone-AFT tablets in a cool, dry place, where the temperature stays below 25 °C.

Keep it where young 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 store it or any other medicine in the bathroom or near a sink. Do not leave it in a car, on a window sill or in the bathroom.

Heat and dampness can destroy some medicines.

Keep it in the blister pack until it is time to take them.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to your pharmacist or any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Methadone-AFT tablets, even if the problem is not listed below.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Stomach and digestion related: <ul style="list-style-type: none">• Vomiting• Constipation Alertness related: <ul style="list-style-type: none">• Drowsiness• Dizziness• Light-headedness• Confusion Body as a whole: <ul style="list-style-type: none">• Nausea• Dry mouth• Sweating• Problems with urine flow• Tolerance and dependence	Speak to your doctor if you have any of these less serious side effects and they worry you. These side effects are common. With prolonged use, the dose may have to be increased to achieve the same benefit, whilst a sudden decrease in dose or interruption of therapy may give rise to withdrawal symptoms.

Serious side effects

Serious side effects	What to do
Breathing related: <ul style="list-style-type: none">• Difficulty in breathing• Wheezing Allergy related: <ul style="list-style-type: none">• Hayfever• Lumpy rash (hives) Body as a whole: <ul style="list-style-type: none">• Fainting• Swelling in the lips/ mouth	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. These could be a symptom of an allergic reaction.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Methadone-AFT contains

Active ingredient (main ingredient)	Methadone hydrochloride
Other ingredients (inactive ingredients)	Lactose monohydrate Starch pregelatinized Magnesium stearate
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What Methadone-AFT looks like

5 mg: Methadone-AFT tablets are white coloured round tablets with 5 on one side and scored on the other side (Aust R 380311).

10 mg: Methadone-AFT tablets are white coloured round tablets with 10 on one side and scored on the other side (Aust R 380312).

Who distributes Methadone-AFT

AFT Pharmaceuticals Pty Ltd.
113 Wicks Road, North Ryde, NSW 2113
Email: customer.service@aftpharm.com

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