

Methadone-AFT

Methadone hydrochloride tablets 5 mg and 10 mg

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using Methadone-AFT.

This leaflet answers some common questions about Methadone-AFT. It does not contain all the available information. It 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 using Methadone-AFT against the benefits they expect it will 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 need to read it again.

What Methadone-AFT is used for

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

Methadone-AFT is used for the treatment of severe pain and treatment of dependence on opioid drugs.

Your doctor may have prescribed Methadone-AFT for another reason.

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

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

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.

Before you use Methadone-AFT

When you must not use it

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:
 - respiratory depression
 - bronchial asthma
 - alcoholism
 - head injury and raised intracranial pressure

- you are taking or have recently taken (within 14 days) antidepressants of the type called monoamine oxidase inhibitors (MAOIs)
- you suffer from ulcerative colitis
- you suffer from hepatic impairment
- 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

If you are not sure whether you should start using Methadone-AFT, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines
- you have cardiac problems
- you are less than 18 years of age
- you are an elderly person, particularly if you are suffering from kidney problems
- you are suffering from hepatic (liver) problems, Hepatitis C or kidney problems
- you are pregnant, or become pregnant while taking Methadone-AFT, are about to give birth, or are breastfeeding
- you intend to drink alcohol while taking Methadone-AFT.

If you have not told your doctor about any of the above, tell them before you start using Methadone-AFT.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Methadone-AFT.

Some medicines may interfere with Methadone-AFT. These include:

Alcohol, benzodiazepines, buprenorphine, carbamazepine, Chlormethiazole, cimetidine, cisapride, domperidone, metoclopramide, cyclizine and other sedating antihistamines, desipramine, other tricyclic antidepressants, erythromycin, fluconazole, fluoxetine, fluvoxamine, other SSRI, grapefruit juice, indinavir, ketoconazole, MAOI including selegiline and moclobemide, naltrexone, naloxone, nevirapine, nifedipine, omeprazole, phenobarbitone, phenytoin, rifampicin, rifabutin, ritonavir, other protease inhibitors, urine acidifiers (e.g. ascorbic acid / Vitamin C), urine alkalizers (e.g. sodium bicarbonate), zidovudine, zopiclone, other opioids, other CNS depressant medicines (e.g. neuroleptics, hyoscine).

These medicines may be affected by Methadone-AFT, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Methadone-AFT.

How to use Methadone-AFT?

How much to take

- For treatment of severe pain, starting oral doses of Methadone-AFT may range from 5 to 10 mg given every 6 to 8 hours or longer and thereafter adjusted as necessary.
- For treatment of dependence on opioid drugs, a dose of 10 to 20 mg by mouth may be given initially and increased as necessary by 5 to 10 mg daily. The dose must not be increased by more than 5 to 10 mg daily, and by no more than 30 mg in any 7-day period. After stabilization, which can often be achieved with a dose of 30 to 50 mg daily (up to a maximum of 80 mg daily), the dose of Methadone is gradually decreased until total withdrawal is achieved. Some treatment schedules for opioid dependence involved prolonged maintenance therapy with Methadone where the daily dose is adjusted carefully for the individual.

How to take it

Swallow the tablet with a glass of water

When and how long to take it

Your doctor will advise you about the dosing schedule.

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.

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.

While you are using Methadone-AFT

Things you must 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.

Stop using Methadone-AFT immediately and contact a doctor immediately if you become pregnant while you are taking the medicine.

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

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Methadone-AFT.

Things you must 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 to

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.

Drinking alcohol

Tell your doctor if you drink alcohol.

It is unwise to drink alcohol while taking Methadone-AFT.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Methadone-AFT.

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

Signs and symptoms of overdose

The symptoms and signs of overdosage with Methadone parallel those for other opioids, namely profound respiratory depression, pin-point pupils, hypotension, circulatory failure and pulmonary oedema and coma.

Mydriasis may replace miosis as asphyxia intervenes. Drowsiness, floppiness, pin-point pupils and apnoea have been reported in children.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Methadone-AFT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

Most frequently observed side effects

The most frequently observed adverse reactions include light headedness, dizziness, sedation, nausea, vomiting, and sweating. These effects seem to be more prominent in ambulatory patients and in those who are not suffering severe pain.

Major hazards

The major hazards of methadone are respiratory depression and, to a lesser degree, systemic hypotension. Respiratory arrest, shock, cardiac arrest, and death have occurred.

Other adverse effects

Other adverse effects include weakness, oedema, headache, cardiovascular (heart and blood pressure) abnormalities, hypogonadism, abdominal pain, anorexia, biliary tract spasm, constipation, dry mouth, glossitis, hematologic (blood-related) abnormalities, weight gain, hypokalaemia, hypomagnesaemia, decreased muscle mass and strength, osteoporosis and fractures, raised intracranial pressure, sedation, agitation, changes of mood, dependence, disorientation, dysphoria, euphoria, hallucinations, insomnia, antidiuretic effect, urinary retention or hesitancy, amenorrhoea, reduced libido and/or potency, reduced ejaculate volume, reduced seminal vesicle and prostate secretions, decreased sperm motility, abnormalities in sperm morphology, pulmonary oedema, respiratory depression, pruritus, urticaria, other skin rashes, and rarely, haemorrhagic urticaria.

Adverse effects related to prolonged use

Maintenance on a stabilised dose: during prolonged administration of methadone, as in a methadone maintenance programme, constipation and sweating often persist and hypogonadism, decreased serum testosterone and reproductive effects are thought to be related to chronic opioid use.

After using Methadone-AFT

Storage

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 pack until it is time to take them.

Disposal

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.

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

Product description

What Methadone-AFT contains

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| 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.

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

Sponsor Details

Methadone-AFT is supplied by:

AFT Pharmaceuticals Ltd.

Auckland

Email: customer.service@aftpharm.com

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