

ASPEN METHADONE SYRUP

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 ASPEN METHADONE SYRUP?

ASPEN METHADONE SYRUP contains the active ingredient methadone hydrochloride. ASPEN METHADONE SYRUP is used for the treatment of severe pain and for the treatment of dependence on opioid drugs.

For more information, see Section [1. Why am I using ASPEN METHADONE SYRUP?](#) in the full CMI.

2. What should I know before I use ASPEN METHADONE SYRUP?

Do not use if you have ever had an allergic reaction to methadone hydrochloride 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, plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with ASPEN METHADONE SYRUP 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 ASPEN METHADONE SYRUP?

- The usual dosage for adults is 1 to 2 mL, taken 3 to 4 times a day, but this dosage may be adjusted by your doctor.
- Do not take more than the recommended dose.

More instructions can be found in Section [4. How do I use ASPEN METHADONE SYRUP?](#) in the full CMI.

5. What should I know while using ASPEN METHADONE SYRUP?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.• Seek medical help immediately if ASPEN METHADONE SYRUP is accidentally taken by a child.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their symptoms seem like yours.
Driving or using machines	<ul style="list-style-type: none">• This medicine 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">• Do not drink alcohol while taking ASPEN METHADONE SYRUP.
Looking after your medicine	<ul style="list-style-type: none">• Store ASPEN METHADONE SYRUP in a cool, dry place where it stays below 25°C. Protect from light.• Keep this medicine where children cannot reach it.

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

6. Are there any side effects?

Common side effects include drowsiness, dizziness, vomiting and sweating.

Serious side effects include symptoms of an allergic reaction such as wheezing, swelling of the lips/mouth, difficulty in breathing and fainting.

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

ASPEN METHADONE SYRUP 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

ASPEN METHADONE SYRUP 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

ASPEN METHADONE SYRUP 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 ASPEN METHADONE SYRUP 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 using ASPEN METHADONE SYRUP

Using ASPEN METHADONE SYRUP with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and 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 using ASPEN METHADONE SYRUP.

ASPEN METHADONE SYRUP

Active ingredient: *methadone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ASPEN METHADONE SYRUP.

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 ASPEN METHADONE SYRUP.

Where to find information in this leaflet:

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

1. Why am I using ASPEN METHADONE SYRUP?

ASPEN METHADONE SYRUP contains the active ingredient methadone hydrochloride. It belongs to a group of medicines called opioid analgesics.

ASPEN METHADONE SYRUP is used for the treatment of severe pain and for the treatment of dependence on opioid drugs.

Addiction

You can become addicted to ASPEN METHADONE SYRUP even if you take it exactly as prescribed. ASPEN METHADONE SYRUP 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 ASPEN METHADONE SYRUP suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to ASPEN METHADONE SYRUP 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.

ASPEN METHADONE SYRUP 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use ASPEN METHADONE SYRUP?

Warnings

Do not use ASPEN METHADONE SYRUP if:

- **you have ever had an allergic reaction to methadone hydrochloride, any other opioid drug or any of the ingredients listed toward the end of this leaflet.**
Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.
- **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) or selective serotonin re-uptake inhibitors (SSRIs).**
- **you suffer from biliary and renal tract spasm**
- **the expiry date printed on the pack has passed**
- **the packaging is torn or shows signs of tampering.**

Check with your doctor if you:

- are under 18 years of age
- are allergic to foods, dyes, preservatives or any other medicines
- are pregnant or become pregnant while taking it
- are about to give birth or are breastfeeding
- have any other medical condition including:
 - hormone problems
 - an underactive thyroid gland
 - diabetes
 - prostate disease
 - phaeochromocytoma, 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, particularly large amounts, while you are taking ASPEN METHADONE SYRUP.

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?](#)

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 of the medicines that may interfere with this medicine include:

- St John's wort
- rifampicin, an antibiotic
- medicines to treat epilepsy
- medicines to treat HIV infections
- fluconazole, an antifungal
- selective serotonin re-uptake inhibitors (SSRIs) which are medicines to treat depression or obsessive compulsive disorders e.g. fluvoxamine
- any other medicines to treat depression
- medicines to treat mental illness
- medicines to treat heart conditions
- other pain relievers, muscle relaxants or tranquilisers
- fluid or water tablets
- laxatives
- fludrocortisone, a medicine used in certain hormone conditions.

You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking this medicine.

Use in children and elderly patients

ASPEN METHADONE SYRUP is not recommended for use in children under 18 years of age.

The doctor may prescribe a smaller dose in elderly patients.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ASPEN METHADONE SYRUP.

4. How do I use ASPEN METHADONE SYRUP?

How much to take

Take this medicine as directed by your doctor or pharmacist.

The usual dosage for adults is 1 to 2 mL, taken 3 to 4 times a day, but this dosage may be adjusted by your doctor.

Do not take more than the recommended dose.

It can result in low blood sugar.

How to take ASPEN METHADONE SYRUP

ASPEN METHADONE SYRUP is designed specifically to be taken by mouth only.

It is not suitable for injection. Injecting this medicine can be extremely hazardous.

How long to take it for

Do not stop taking this medicine or change the dose without first checking with your doctor.

Your doctor may want to gradually reduce the amount you are taking before stopping completely in order to lessen the chance of possible withdrawal side effects.

If you use too much ASPEN METHADONE SYRUP

You will usually take your dose under the supervision of your pharmacist or doctor who has calculated the appropriate amount for you. Therefore, overdose should not normally occur. Take home doses have also been calculated specifically for you and should not result in an overdose.

If you think that you or someone other than you have used too much ASPEN METHADONE SYRUP, urgent medical attention is needed.

Keep the person awake by talking to them or gently shaking them every now and then.

Symptoms of overdose include:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea, vomiting
- convulsions, fits
- confusion, memory loss
- difficulty walking
- changes in behaviour or personality.

You should immediately:

- phone triple zero (000) for an ambulance, or
- 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.

Report any other medicine or alcohol which has been taken.

5. What should I know while using ASPEN METHADONE SYRUP?

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.

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 medicine more often than recommended by your doctor.

Seek medical help immediately if ASPEN METHADONE SYRUP is accidentally taken by a child.

Things you should not do

Do not give this medicine to anyone else, even if their symptoms seem like yours.

Do not use it to treat any other complaints unless your doctor says to.

Things to be careful of

Particular care should be taken when starting this medicine or increasing the dose. Methadone 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

ASPEN METHADONE SYRUP may cause dizziness in some people. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required.

Drinking alcohol

Do not drink alcohol while taking ASPEN METHADONE SYRUP.

Looking after your medicine

Store ASPEN METHADONE SYRUP in a cool, dry place where it stays below 25°C. Protect from light.

Keep this medicine where children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

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 possible withdrawal symptoms.

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
<ul style="list-style-type: none"> drowsiness fatigue lack of appetite sleep disturbances such as a sudden awakening from sleep with shortness of breath trouble with sleeping (either not enough or too much) snoring weakness dizziness light-headedness nausea and vomiting severe stomach pain that may be felt in the back fever and chills changes in bowel habits dry mouth sweating confusion problems with urine flow low blood pressure tolerance and dependence. 	<p>Speak to your doctor or pharmacist if you have any of these less serious, common side effects and they worry you.</p>
<ul style="list-style-type: none"> decreased libido impotence absence of menstruation trouble swallowing chest discomfort such as pressure, heartburn or tightness. 	<p>Speak to your doctor if you have any of these side effects that may be associated with long-term use.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction including:</p> <ul style="list-style-type: none"> wheezing swelling of the lips/mouth difficulty in breathing hayfever lumpy rash (hives) fainting. 	<p>Phone triple zero (000) for an ambulance, call your doctor straight away or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

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 ASPEN METHADONE SYRUP contains

Active ingredient (main ingredient)	methadone hydrochloride 5 mg/mL
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> sodium benzoate ethanol sorbitol solution 70% (non-crystallising) glycerol sunset yellow FCF anise spice SC491233 purified water.
Potential allergens	<ul style="list-style-type: none"> benzoate alcohol <p>Contains 4.4% v/v ethanol.</p> <ul style="list-style-type: none"> sorbitol. <p>Contains 6.2 g of sorbitol per recommended maximum daily dose. Products containing sorbitol</p>

	may have a laxative effect or cause diarrhoea.
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Do not take this medicine if you are allergic to any of these ingredients.

ASPEN METHADONE SYRUP is lactose, sucrose and gluten free.

What ASPEN METHADONE SYRUP looks like

ASPEN METHADONE SYRUP is a bright, amber-coloured syrup with an aromatic odour. It is available in either a 200 mL or 1 L brown HDPE bottle with a child-resistant cap.

Australian Registration number: AUST R 49372.

Who distributes ASPEN METHADONE SYRUP

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

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