

ASPEN METHADONE SYRUP

methadone hydrochloride

Consumer Medicine Information

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.

What is in this leaflet

This leaflet answers some common questions about ASPEN METHADONE SYRUP. It does not contain all of 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 taking this medicine against the benefits they expect it will have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What it is used for

ASPEN METHADONE SYRUP contains the active ingredient, methadone hydrochloride. It

belongs to a group of medicines called opioid analgesics.

It 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.

ASPEN METHADONE SYRUP is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take 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 (EXP) printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if:

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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.

How to take it

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 it

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 take too much (overdose)

If you or someone else receive too much (overdose) and experience one or more of the symptoms below, immediately call triple zero (000) 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 used ASPEN METHADONE SYRUP 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.

If you think you or someone else may have used too much ASPEN METHADONE SYRUP, 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.

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 have been taken.

While you are taking it

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.

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.

Things you must not do

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

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

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

Things to be careful of

This medicine may cause drowsiness. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required.

Do not drink alcohol while taking ASPEN METHADONE SYRUP.

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.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking ASPEN METHADONE SYRUP.

All medicines 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 side effects.

Common side-effects are:

- drowsiness
- dizziness
- light-headedness
- nausea
- vomiting
- dry mouth
- sweating
- confusion
- constipation
- problems with urine flow
- tolerance and dependence.

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.

Tell your doctor immediately if you notice any of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hayfever
- lumpy rash (hives)
- fainting.

These could be a symptom of an allergic reaction.

Tell your doctor 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.

After taking it

Storage

Keep 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.

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

Do not leave in a car, on a window sill or in the bathroom.

Disposal

Return any unused or expired medicine to your pharmacist.

Product description

What it looks like

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

Ingredients

ASPEN METHADONE SYRUP contains methadone hydrochloride 5 mg/mL as the active ingredient.

It also contains the following inactive ingredients:

- sodium benzoate
- ethanol
- sorbitol solution 70% (non-crystallising)
- glycerol
- sunset yellow FCF
- anise spice SC491233
- purified water.

ASPEN METHADONE SYRUP is lactose, sucrose and gluten free.

Sponsor

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

Australia Registration Number:
AUST R 49372

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