

ASPEN METHADONE SYRUP™

methadone hydrochloride

Consumer Medicine Information

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.

People who take ASPEN METHADONE SYRUP for a long time to treat their pain rarely become addicted to it. However, with time, your body will become used to taking this medicine and you may experience symptoms due to withdrawal if you suddenly stop taking it. These symptoms may include body aches, diarrhoea, nervousness, shivering, nausea,

sleep disturbance, sweating, weakness and fever.

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
 - 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

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.

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)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, or go to the Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too much ASPEN METHADONE SYRUP. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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, such as in a locked cupboard.

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
- exacol caramel R4081
- 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

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AUST R 49372

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