

ALFENTANIL-HAMELN INJECTION

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 being given Alfentanil-hameln?

Alfentanil-hameln contains the active ingredient alfentanil hydrochloride. Alfentanil-hameln is used to relieve pain and produce anaesthesia.

For more information, see [Section 1. Why am I being given Alfentanil-hameln?](#) in the full CMI.

2. What should I know before I am given Alfentanil-hameln?

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

For more information, see [Section 2. What should I know before I am given Alfentanil-hameln?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food store, may interfere with Alfentanil-hameln 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 will I be given Alfentanil-hameln?

- Your doctor will decide the appropriate dose for you.
- Alfentanil-hameln must only be administered by injection by a specially trained anaesthetist.

Follow the instructions given to you by your doctor or pharmacist exactly. More instructions can be found in [Section 4. How will I be given Alfentanil-hameln?](#) in the full CMI.

5. What should I know while using Alfentanil-hameln?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Alfentanil-hameln• Tell your doctor or pharmacist if you are taking any other medicines that you use to help you relax, anything that contains alcohol (like cough syrup) or other medicines that treat pain• If you become pregnant while being given this medicine, tell your doctor immediately
Driving or using machines	<ul style="list-style-type: none">• Alfentanil-hameln may affect your alertness and ability to drive. Therefore you should not drive or operate machinery until your doctor advises that you can.
Drinking alcohol	<ul style="list-style-type: none">• You must not drink alcohol while being given Alfentanil-hameln• Tell your doctor about your consumption of alcohol and follow the doctor's advice.

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

6. Are there any side effects?

Alfentanil-hameln injection may cause nausea, dizziness and/or drowsiness, and be habit forming if taken frequently or over long periods.

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.

Alfentanil-hameln Injection

Active ingredient(s): *Alfentanil Hydrochloride*

WARNING

Limitations of use

Alfentanil-hameln 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

Alfentanil-hameln 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

Alfentanil-hameln 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 Alfentanil-hameln 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 Alfentanil-hameln

Using Alfentanil-hameln with other medicines that can make you feel drowsy such as sleeping tablets (eg. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (eg. 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 Alfentanil-hameln.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Alfentanil-hameln. 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 Alfentanil-hameln.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Alfentanil-hameln against the benefits they expect it will have for you.

Where to find information in this leaflet:

1. [Why am I being given Alfentanil-hameln?](#)
2. [What should I know before I am given Alfentanil-hameln?](#)
3. [What if I am taking other medicines?](#)
4. [How will I be given Alfentanil-hameln?](#)
5. [What should I know while being given Alfentanil-hameln?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given Alfentanil-hameln?

Alfentanil-hameln contains the active ingredient alfentanil hydrochloride. Alfentanil belongs to a group of medicines called opioid analgesics and works by changing the messages that are sent to the brain about pain.

Alfentanil-hameln is used to relieve pain and produce anaesthesia. It can be used as a premedication before an operation, or with a general anaesthetic during an operation.

Your doctor, however, may have prescribed it for another purpose, and will have explained why you are being given Alfentanil-hameln.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

2. What should I know before I am given Alfentanil-hameln?

When you must not use it:

- Alfentanil-hameln should not be used for pain relief after surgery has taken place.
- Alfentanil-hameln should not be used if you have an allergy, intolerance or hypersensitivity to:
 - alfentanil;
 - any ingredients listed at the end of this leaflet;
 - other opioid analgesics (pain killers), eg. morphine or pethidine.

Symptoms of an allergic or hypersensitivity reaction may include:

- rash, itching or hives on the skin;
- shortness of breath, wheezing or difficulty breathing;

- swelling of the face, lips, tongue or other parts of the body.

Alfentanil-hameln is not generally given to children under 12 years of age.

Alfentanil-hameln injection will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not passed.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any medical conditions, especially the following:
 - problems with your breathing such as severe asthma, severe bronchitis or emphysema;
 - a history of fits or head injury;
 - under-active thyroid;
 - myasthenia gravis (muscle weakness);
 - heart problems;
 - liver or kidney problems;
 - overweight or obese.
- or anyone in your family has ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses

Tell your doctor if you take any medicine that slows down your reactions (CNS depressants), especially benzodiazepines or related drugs or have problems with alcohol.

It may not be safe for you to be given Alfentanil-hameln or you may be given a reduced dose if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you are given Alfentanil-hameln.

Pregnancy and breastfeeding

Tell your doctor if:

- you are pregnant or planning to become pregnant. Your doctor will decide if you can take Alfentanil-hameln. It may affect your baby if it is given early in pregnancy or in the last weeks before your baby is due.
- you are breastfeeding or wish to breastfeed. Alfentanil-hameln may be excreted in breast milk. Breastfeeding is not advisable for 24 hours after Alfentanil-hameln has been given.

Addiction

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

Dependence

Repeated use of Alfentanil-hameln may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Alfentanil-hameln, it is important that you consult your doctor.

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

Tolerance

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

If this happens, your doctor may review the dose so that you get adequate pain relief.

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.

Alfentanil-hameln given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn. Also, if women receive this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food store.

Tell your doctor immediately and do not take Alfentanil-hameln if you are taking medicines for depression called Monoamine Oxidase (MAO) Inhibitors. These medicines must not be taken in the 14 days before Alfentanil-hameln is given.

Also tell your doctor if you are taking:

- any anaesthetic agents such as propofol.
 - any medicine that slows down your reactions (CNS depressants) such as benzodiazepines or related drugs, sleeping pills, tranquillizers, medicines for mental disorders, alcohol, some illegal drugs.
- If you receive a strong pain killer or other CNS depressant after receiving Alfentanil-hameln during surgery, the dose of the pain killer or other

CNS depressant may need to be lowered to reduce the risk of potentially serious side effects such as breathing difficulties, with slow or shallow breathing, severe drowsiness and decreased awareness, coma and death. Using opioids at the same time as drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.

- an antibiotic called erythromycin.
- an antifungal called fluconazole, voriconazole, ketoconazole or itraconazole.
- a medicine for the stomach called cimetidine.
- an antiviral called ritonavir.
- a heart medicine called diltiazem.
- medicines for depression known as selective serotonin re-uptake inhibitors (SSRIs) or serotonin norepinephrine re-uptake inhibitors (SNRIs).

Alfentanil-hameln can increase the effects of alcohol. Tell your doctor about your consumption of alcohol and follow the doctor's advice.

If you have not told your doctor about any of these things, tell them before you are given Alfentanil-hameln.

These medicines may be affected by Alfentanil-hameln or may affect how well Alfentanil-hameln works. Your doctor can tell you what to do if you are taking any of these medicines.

4. How will I be given Alfentanil-hameln?

Alfentanil-hameln will be given to you by injection by a specially trained anaesthetist.

The injection is given into the vein (intravenous use).

Your doctor will decide how much Alfentanil-hameln you will need.

Elderly people may be given a smaller dose.

If you are given too much Alfentanil-hameln

The doctor or nurse giving you Alfentanil-hameln will be experienced in its use, so it is extremely unlikely that you will be given too much.

In the unlikely event that an overdose occurs, your doctor or the anaesthetist will take the necessary actions. The symptoms of overdose could include:

- slow, unusual or difficult breathing;
- drowsiness, dizziness or unconsciousness;
- slow or weak heartbeat;
- nausea or vomiting;
- convulsions or fits;
- muscle stiffness;
- lowering of blood pressure;
- lowering of heart rate.

If these symptoms occur, you may be administered another medicine (eg. naloxone) to help reverse the effects.

If you think you or anybody else has been given too much Alfentanil-hameln, immediately contact your doctor or nurse, or phone the Poisons Information Centre (telephone 13 11 26).

5. What should I know while being given Alfentanil-hameln?

Things you must do

Before you start on a new medicine, remind your doctor and pharmacist that you are being given Alfentanil-hameln injection or infusion. Tell any other doctors, dentists and pharmacists who treat you that you are having this medicine.

If you become pregnant while being given this medicine, tell your doctor immediately.

Driving or using machines

Alfentanil-hameln may affect your alertness and ability to drive. Therefore you should not drive or operate machinery until your doctor advises that you can.

Drinking alcohol

You must not drink alcohol while you are being given this medicine.

Drinking alcohol whilst using Alfentanil-hameln injection or infusion may result in severe drowsiness, decreased awareness, breathing problems, coma and death.

Looking after your medicine

Store unopened Alfentanil-hameln ampoules in a cool dry place, where the temperature stays below 30°C.

Alfentanil-hameln will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

Alfentanil-hameln should not be used after the date printed on the label has passed. The anaesthetist will inspect Alfentanil-hameln before use to determine that it is still within its expiry date.

Getting rid of any unwanted medicine

The hospital staff looking after you will dispose of any remaining Alfentanil-hameln appropriately.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well after you have been given Alfentanil-hameln.

Alfentanil-hameln helps most people suffering severe pain, but it may have unwanted side effects in a few people. 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 side effects.

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

After you have been given Alfentanil-hameln you will probably feel light-headed, dizzy, sleepy and you may feel quite strange, especially if you are not lying down.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">nausea and vomiting;dizziness;drowsiness or sleepiness;injection site pain or pain during the procedure.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

The following list includes serious side effects that may require medical attention.

Serious side effects	What to do
<ul style="list-style-type: none">feeling of extreme happiness (euphoric mood);visual disturbance such as blurred vision;chills;rashbreathing difficulties, which can last longer than its pain-killing effect;slow, fast or irregular heartbeat;tightening of the chest or heart attack;low or high blood pressure;muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements;spasm of the larynx (voice box).	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.

Tell your doctor, nurse 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 Alfentanil-hameln contains

Active ingredient (main ingredient)	Alfentanil hydrochloride
Other ingredients (inactive ingredients)	sodium chloride hydrochloric acid water for injections

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

What Alfentanil-hameln looks like

Alfentanil-hameln solution for injection or infusion is available in glass ampoules containing a clear, colourless solution. It is available in two presentations:

- 1 mg in 2 mL (AUST R 386331)
- 5 mg in 10 mL (AUST R 386330)

Alfentanil-hameln 1 mg/2 mL and 5 mg/10 mL solution for injection or infusion are supplied in packs of 5 and 10 ampoules.

Who distributes Alfentanil-hameln

hameln pharma Pty Ltd
Level 3, 302 Burwood Rd
Hawthorn, Victoria 3122
Australia

mail@hameln-pharma.com.au

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