

Alfentanil GH

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.

1. Why am I using Alfentanil GH?

Alfentanil GH contains the active ingredient (alfentanil hydrochloride). Alfentanil GH is a drug used to relieve pain and produce anesthesia. For more information, see Section [1. Why am I using Alfentanil GH?](#) in the full CMI.

2. What should I know before I use Alfentanil GH?

Do not use if you have ever had an allergic reaction to Alfentanil or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have other medical conditions, take other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take Alfentanil GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Alfentanil GH and affect how it works or may be affected by Alfentanil GH. 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 Alfentanil GH?

- Alfentanil GH 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 GH you will need.

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

5. What should I know while using Alfentanil GH?

Things you should do	<ul style="list-style-type: none">Remind any doctor, surgeon, dentist or pharmacist you visit that you are taking Alfentanil GH.Drink enough water during exercise and hot weather when you are taking Alfentanil GH.Tell your doctor if: you are pregnant or planning to become pregnant. Your doctor will decide if you can take Alfentanil GH. It may affect your baby if it is given early in pregnancy or in the last weeks before your baby is due.
Things you should not do	<ul style="list-style-type: none">Do not use Alfentanil GH to treat any other complaints unless your doctor or pharmacist tells you to.Alfentanil GH should not be used for pain relief after surgery has taken place.Do not stop taking Alfentanil GH suddenly, or change the dosage, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Alfentanil GH affects you.Alfentanil GH may cause drowsiness, dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">You should avoid drinking alcohol when taking Alfentanil GH. Tell your doctor about your consumption of alcohol and follow the doctor's advice.
Looking after your medicine	<ul style="list-style-type: none">Store it in a cool dry place below 25°C Do not freeze. Protect from light.

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

6. Are there any side effects?

Speak to your doctor if you have any of these less serious side effects and they worry you: dizziness, drowsiness, nausea and vomiting, feeling sick, nausea, problems sleeping, injection site pain or pain during the procedure. Tell your doctor as soon as possible if you notice any of these symptoms: feeling of extreme happiness (euphoric mood), visual disturbance such as blurred vision, chills, rash. 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: 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).

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

Alfentanil GH 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 GH 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 GH 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 GH 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 GH

Using Alfentanil GH 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 GH.

Alfentanil GH

Active ingredient(s): *alfentanil hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Alfentanil GH. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Alfentanil GH.**

Where to find information in this leaflet:

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

1. Why am I using Alfentanil GH?

Alfentanil GH contains the active ingredient alfentanil hydrochloride. Alfentanil GH is a drug 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.

Alfentanil GH belongs to a group of medicines called opioid analgesics. Alfentanil GH works by changing the messages that are sent to the brain about pain. Your doctor will have explained why you are being given Alfentanil GH.

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

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed Alfentanil GH for another use. Ask your doctor if you want more information.

2. What should I know before I use Alfentanil GH?

Warnings

Do not use Alfentanil GH 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 GH is not generally given to children under 12 years of age.

Alfentanil GH 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:

- are pregnant or planning to become pregnant. Your doctor will decide if you can take Alfentanil GH. It may affect your baby if it is given early in pregnancy or in the last weeks before your baby is due.
- are breastfeeding or wish to breastfeed. Alfentanil GH may be excreted in breast milk. Breastfeeding is not advisable for 24 hours after Alfentanil GH has been given.
- or anyone in your family have 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.
- Alfentanil GH can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.
- Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.
- Adrenal insufficiency symptoms such as weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure.
- Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops.
- have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time.

Tell your doctor if you have any of the following medical conditions:

- 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

This medicine contains alfentanil which is an opioid medicine. Repeated use of opioid painkillers 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 GH, it is important that you consult your doctor.

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?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor or pharmacist can discuss the risks and benefits involved.

3. What if I am taking other medicines?

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 GH 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 GH.

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 GH if you are taking:

- medicines for depression called Monoamine Oxidase (MAO) Inhibitors. These medicines must not be taken in the 14 days before Alfentanil GH 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 GH 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. The concomitant use of opioids and

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 GH 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 GH.

These medicines may be affected by Alfentanil GH or may affect how well Alfentanil GH works.

Your doctor can tell you what to do if you are taking any of these medicines

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

Addiction

You can become addicted to Alfentanil GH even if you take it exactly as prescribed. Alfentanil GH 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 Alfentanil GH. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Alfentanil GH suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Alfentanil GH 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.

Alfentanil GH 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.

4. How do I use Alfentanil GH?

How much to take

Alfentanil GH 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 GH you will need.

Elderly people may be given a smaller dose.

When to take Alfentanil GH.

Alfentanil GH 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.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

If you forget to take Alfentanil GH

Alfentanil GH should be taken regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember (with food), and then go back to taking your dose as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much Alfentanil GH

If you think that you have used too much Alfentanil GH, you may need urgent medical attention.

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy)

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.

5. What should I know while using Alfentanil GH?

Things you should not do

- Alfentanil GH should not be used for pain relief after surgery has taken place.
- Alfentanil GH is not generally given to children under 12 years of age.

Driving or using machines

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

Be careful before you drive or use any machines or tools until you know how Alfentanil GH affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Store unopened Alfentanil GH ampoules in a cool dry place, where the temperature stays below 25°C. Do not freeze. Protect from the light. for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Alfentanil GH 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 GH 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">• dizziness;• drowsiness or sleepiness;• injection site pain or pain during the procedure;• nausea and vomiting;• Pancreatitis• Adrenal insufficiency and Androgen deficiency	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

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;• rash;• breathing 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).• Spasm of sphincter of Oddi• Central sleep apnoea syndrome	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 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 GH contains

Active ingredient (main ingredient)	Alfentanil (as hydrochloride).
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Hydrochloric acid• Sodium Chloride• Water for injections.

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

What Alfentanil GH looks like

Alfentanil GH is a clear, colourless solution.

Alfentanil GH is available in 2 mL or 10 mL glass ampoules in cartons of 1, 5 or 10 ampoules*.

* Not all pack sizes may be marketed.

Alfentanil GH 1 mg/2 mL: AUST R 200007

Alfentanil GH 5 mg/10 mL: AUST R 199999

Who distributes Alfentanil GH

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill VIC 3128

Email: ghinfo@generichealth.com.au

Phone: +61 3 9809 7900

Website: www.generichealth.com.au

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