

ALFENTANIL

Alfentanil hydrochloride

New Zealand Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Medsurge Alfentanil injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Alfentanil injection against the benefits they expect it will give you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What Alfentanil injection is used for

Alfentanil injection 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 injection belongs to a group of medicines called opioid analgesics.

Alfentanil injection works by changing the messages that are sent to the brain about pain.

Your doctor will have explained why you are being given Alfentanil injection.

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 this medicine has been prescribed for you. Your doctor may have prescribed it for another purpose.

Before you are given Alfentanil injection

When you must not use Alfentanil injection

Alfentanil injection should not be used for pain relief after surgery has taken place.

Alfentanil injection 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) e.g. 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 injection should not be given to children under 1 year of age.

Alfentanil 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.

If you are not sure whether you should start having this medicine, talk to your doctor.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant. Ask your doctor about the risks and benefits involved.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

As alfentanil may be excreted in breast milk, breast-feeding is not advisable for 24 hours after alfentanil has been given.

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

- problems with your breathing such as severe asthma, severe bronchitis or emphysema, history of fits or head injury
- under-active thyroid
- myasthenia gravis (muscle weakness)
- heart problems
- liver or kidney problems
- are overweight or obese
- if you take any medicines that slows down your reactions (CNS depressants), especially benzodiazepines or related drugs.

It may not be safe for you to be given Alfentanil injection 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 injection.

Your doctor may not want to give you this medicine or may want to take special precautions if you have any of the above conditions.

Taking other medicines

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

Tell your doctor immediately and if you are taking:

- medicines for depression called Monoamine Oxidase (MAO) Inhibitors. These medicines must not be taken in the 14 days before Alfentanil injection 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, medicine for mental disorders, alcohol, some illegal drugs.

If you receive a strong pain killer or other CNS depressant after receiving Alfentanil injection during surgery, the dose of the painkiller or other CNS depressants 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.

- 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 injection 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 injection.

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

Taking Alfentanil injection

How much is given

Your doctor will decide how much Alfentanil injection you will receive. Elderly people may be given a smaller dose.

How is it given

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

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

If you have too much (Overdose)

The doctor or nurse giving you Alfentanil injection 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:

- breathing difficulties

- muscle stiffness
- lowering of blood pressure
- lowering of heart rate.

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

If you think you or anybody else has been given too much Alfentanil injection, contact your doctor or nurse immediately.

Side effects

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

Alfentanil injection 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 injection you will probably feel light-headed, dizzy, sleepy and you may feel quite strange, especially if you are not lying down.

Tell your doctor or nurse if you notice any of the following side effects and they worry you:

- nausea and vomiting
- dizziness
- drowsiness or sleepiness
- injection site pain or pain during the procedure.

Tell your doctor or nurse as soon as possible if you have any of the following as you may need medical attention:

- feeling of extreme happiness (euphoric mood)
- visual disturbance such as blurred vision
- chills
- rash.

Tell your doctor or nurse immediately if you experience:

- 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).

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

Some people may get other side effects after being given Alfentanil injection. **Tell your doctor or nurse if you notice anything else that is making you feel unwell.**

After being given Alfentanil injection

Storage

Alfentanil injection will be stored in the pharmacy or on the ward.

Store the ampoules in a cool dry place below 25 degrees Celsius (room temperature).

Product is for single use in one patient only. Discard any residue.

Disposal

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

Product description

What it looks like

Medsurge Alfentanil injection comes in a 2 mL or a 10 mL clear glass ampoule containing a clear colourless solution.

There are different presentations and pack sizes available:

| Presentation | Pack size |
|---------------------|-------------------------------------|
| 1 mg/2 mL | 1 x 2 mL, 5 x 2 mL and 10 x 2 mL |
| 5 mg/10 mL | 1 x 10 mL, 5 x 10 mL and 10 x 10 mL |

Not all presentations and/or packs are marketed.

Ingredients

The active ingredient in Medsurge Alfentanil injection is alfentanil. Medsurge Alfentanil injection contains 0.5 mg/mL of alfentanil, as well sodium chloride, sodium hydroxide (to adjust pH) and water for injections.

Each 2 mL ampoule contains 1.0 mg of alfentanil.

Each 10 mL ampoule contains 5.0 mg of alfentanil.

Sponsor

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This leaflet was prepared in April 2025.