

# Medsurge Alfentanil

## 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 using Medsurge Alfentanil?

Medsurge Alfentanil contains the active ingredient alfentanil hydrochloride. Medsurge Alfentanil 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.

For more information, see Section [1. Why am I using Medsurge Alfentanil?](#) in the full CMI.

### 2. What should I know before I use Medsurge Alfentanil?

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

**Talk to your doctor if you have any other medical conditions, take any 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 use Medsurge Alfentanil?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Medsurge Alfentanil 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 I use Medsurge Alfentanil?

- Your doctor will decide how much alfentanil you will need. Elderly people may be given a smaller dose.

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

### 5. What should I know while using Medsurge Alfentanil?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using alfentanil</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Alfentanil may affect your alertness and ability to drive. Therefore, you should not drive or operate machinery until your doctor advised that you can</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Alfentanil can increase the effects of alcohol. Tell your doctor about your consumption of alcohol and follow the doctor's advice</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Medsurge Alfentanil should be kept in a cool dry place, protected from light, where the temperature stays below 25 degrees C.</li></ul>

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

### 6. Are there any side effects?

The following Less serious side effects: feeling of extreme happiness (euphoric mood), visual disturbance such as blurred vision, chills, rash as you may need medical attention.

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 injection 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 injection 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 injection 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 injection 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 injection**

Using Alfentanil injection 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 Alfentanil injection.

# Medsurge Alfentanil

Active ingredient(s): *alfentanil*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Medsurge Alfentanil. **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 Medsurge Alfentanil.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Medsurge Alfentanil?

Medsurge Alfentanil contains the active ingredient **alfentanil hydrochloride**. Alfentanil is a potent, short-acting opioid analgesic chemically related to fentanyl.

Medsurge Alfentanil 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.

## 2. What should I know before I use Medsurge Alfentanil?

### Warnings

**Do not use Medsurge Alfentanil if:**

- you are allergic to alfentanil hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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: other opioid analgesics (pain killers) e.g. morphine or pethidine.

**Check with your doctor if you:**

- have any other 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
    - are overweight or obese
  - take any medicines for any other condition
- 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 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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.

It may affect your baby if it is given early in pregnancy or in the last weeks before your baby is due.

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

Alfentanil may be excreted in breast milk. Breastfeeding is not advisable for 24 hours after alfentanil has been given.

## **You must tell your doctor if you:**

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

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 lifethreatening overdose. If you have concern that you may become dependent on alfentanil, it is important that you consult your doctor.

## **3. What if I am taking other medicines?**

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

### **Tell your doctor immediately and do not take alfentanil if you are taking:**

- medicines for depression called Monoamine Oxidase (MAO) Inhibitors. These medicines must not be taken in the 14 days before alfentanil is given.
- 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 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. 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 can increase the effects of alcohol. Tell your doctor about your consumption of alcohol and follow the doctor's advice.

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

## **4. How do I use Medsurge Alfentanil?**

### **How much to take / use**

- Medsurge Alfentanil 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 Medsurge Alfentanil you will need.
- Elderly people may be given a smaller dose.

### **If you use too much Medsurge Alfentanil**

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

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

### **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 Medsurge Alfentanil?**

### **Things you should do**

Remind any doctor, dentist or pharmacist you visit that you are using Medsurge Alfentanil.

## Things you should not do

- Do 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.

## Driving or using machines

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

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.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

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

## Looking after your medicine

- Medsurge Alfentanil should be kept in a cool dry place, protected from light, where the temperature stays below 25 degrees C.
- Medsurge Alfentanil will be kept in a locked cupboard in the hospital pharmacy or operating theatre.
- Medsurge Alfentanil should not be used after the date (month and year) printed after "EXP". The anaesthetist will inspect Medsurge Alfentanil before use to determine that it is still within its use by date.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

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

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.

### Less serious side effects

Less serious side effects	What to do
• nausea and vomiting	<b>Speak to your</b>

<ul style="list-style-type: none"><li>• dizziness</li><li>• drowsiness or sleepiness</li><li>• injection site pain or pain during the procedure</li></ul>	<b>doctor if you have any of these less serious side effects and they worry you.</b>
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• feeling of extreme happiness (euphoric mood)</li><li>• visual disturbance such as blurred vision</li><li>• chills</li><li>• rash</li></ul>	<b>Speak to your doctor or nurse as soon as possible if you have any of these less serious side effects and you may need medical attention.</b>

### Very serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none"><li>• breathing difficulties, which can last longer than its pain-killing effect.</li><li>• slow, fast or irregular heartbeat.</li><li>• tightening of the chest or heart attack</li><li>• low or high blood pressure</li><li>• muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements</li><li>• spasm of the larynx (voice box)</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b>

**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](http://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 Medsurge Alfentanil contains

<b>Active ingredient (main ingredient)</b>	alfentanil hydrochloride
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Water for injections Sodium hydroxide
<b>Potential allergens</b>	none

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

## What Medsurge Alfentanil looks like

Medsurge Alfentanil injection is a clear colourless solution, available in Type 1 clear glass ampoules in the following presentations and pack sizes:

Strength	Pack Sizes (Ampoules)
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 pack sizes are marketed.

## Who distributes Medsurge Alfentanil

Medsurge Pharma Pty Ltd  
Unit 1&2, 6-7 Gilda Court  
Mulgrave, Victoria 3170

## Marketed and Distributed by Medsurge Healthcare.

Telephone: 1300 788 261

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