



CONSUMER MEDICINE INFORMATION

Alfentanil GH Injection

Alfentanil (as hydrochloride) 0.5 mg/mL

What is in this leaflet

This leaflet answers some common questions about Alfentanil GH Injection.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of your treatment using Alfentanil GH Injection against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Alfentanil GH Injection is used for

The name of your medicine is Alfentanil GH Injection. It contains the active ingredient called alfentanil (as hydrochloride).

Alfentanil GH 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 GH Injection belongs to a group of medicines called opioid (narcotic) analgesics.

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

Your doctor will have explained why you are being treated with Alfentanil GH Injection and told you what dose you will be given.

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

Your doctor may have prescribed Alfentanil GH Injection for another reason. Ask your doctor if you have any questions about why Alfentanil GH Injection has been prescribed for you.

This medicine is available only with a doctor's prescription.

Alfentanil GH Injection can be addictive, but when it is used only to relieve or prevent pain it is unlikely to become habit forming.

Before you take Alfentanil GH Injection

When you must not take it

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

Alfentanil GH Injection is not generally given to children under 12 years.

You should not be given Alfentanil GH Injection if you are pregnant or breastfeeding unless your doctor says it is safe.

Ask your doctor about the risks and benefits involved.

We do not know if it is safe for you to be given Alfentanil GH Injection while you are pregnant.

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

Breast-feeding is not advisable for 24 hours after Alfentanil GH Injection has been given.

Alfentanil GH Injection must only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

Do not use Alfentanil GH Injection if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Alfentanil GH Injection, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- **you have been given Alfentanil GH Injection before and had any problems with it**
- **you have any allergies to**
 - * any ingredients listed at the end of this leaflet;
 - * other opioid analgesics (pain killers) e.g. morphine or pethidine; or
 - * any other substances.
- **you have any of these 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; or
 - * excessive weight

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

How Alfentanil GH Injection is given

Alfentanil GH Injection will be given to you by injection by specially trained anaesthetists.

The injection is given into a vein.

Your Doctor will decide how much Alfentanil GH Injection you will need.

Elderly people may be given a smaller dose.

If you take too much (overdose)

The doctor or nurse giving you Alfentanil GH 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 has been given, 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

Alfentanil GH Injection doses should be carefully worked out, so problems with overdosage are unlikely. There are drugs, e.g. naloxone or nalorphine, which can be used if needed to reverse the effects of too much Alfentanil GH Injection.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Alfentanil GH Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Side effects

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

Alfentanil GH 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 GH 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.

Alfentanil GH Injection may cause:

- breathing difficulties
- muscle stiffness
- slowed heart beat
- nausea and vomiting

Alfentanil GH Injection can cause breathing difficulties, which can last longer than its pain-killing effect.

Alfentanil GH Injection

sometimes causes:

- low blood pressure
- dizziness
- spasm of the larynx (voice box)
- rash
- blurred vision
- missed or irregular heart beats

Some people may get other side effects after being given Alfentanil GH Injection.

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

Tell your doctor if you notice anything else that is making you feel unwell.

After using Alfentanil GH Injection

Storage

Store unopened Alfentanil GH Injection ampoules in a cool dry place, where the temperature stays below 25°C. Do not freeze. Protect from light.

Alfentanil GH Injection will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

Alfentanil GH Injection should not be used after the date (month and year) printed after "EXP". The anaesthetist will inspect Alfentanil GH Injection before use to determine that it is still within its use by date.

Disposal

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

Product description

What it looks like

Alfentanil GH Injection is a clear, colourless solution.

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

The 2 mL ampoule contains 1 mg of alfentanil.

The 10 mL ampoule contains 5 mg of alfentanil.

*Not all pack sizes may be marketed.

Ingredients

Active ingredient:

- alfentanil

Other ingredients:

- sodium chloride
- hydrochloric acid
- water for injections

Australian Registration Numbers

1 mg/2 mL AUST R 200007

5 mg/10 mL AUST R 199999

SPONSOR

Horizon Hospital Healthcare Pty Ltd
3 Walnut Street
Carnegie, VIC 3163

Distributor

Alfentanil GH Injection is supplied in Australia by:

Generic Health Pty Ltd
Level 1, 1102 Toorak Road
Camberwell VIC 3124

This leaflet was prepared in November 2013.