PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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Alfentanil 500 micrograms/ml solution for injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or nurse.*
- *If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.*

This medicine contains alfentanil which is an opioid, which can cause addiction.
You can get withdrawal symptoms if you stop taking it suddenly.

The name of your medicine is Alfentanil 500 micrograms/ml solution for injection, which will be referred to as Alfentanil throughout this leaflet.

What is in this leaflet

1. WHAT ALFENTANIL IS AND WHAT IT IS USED FOR

Alfentanil belongs to a class of medicines called opioids, which relieve or prevent pain. Alfentanil is a strong painkiller which has a very rapid effect. Alfentanil is used for surgical procedures.

Alfentanil is used in adults for:
- Short procedures and outpatient surgery (day case)
- Medium and long procedures when given as an injection and followed by additional doses or by continuous infusion

Alfentanil is used in neonates, infants and children:
- for induction of anaesthesia
- as a pain killer during anaesthesia and for both short and long surgical procedures

At very high doses, Alfentanil may be used to induce unconsciousness (anaesthesia) in patients with assisted breathing (artificially ventilated patients).

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop receiving it suddenly. Your prescriber should have explained how long you will be receiving it for and when it is appropriate to stop, how to do this safely.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ALFENTANIL

You should NOT be given Alfentanil if:
- you are **allergic** (hypersensitive) to **Alfentanil**, other **strong painkillers (opioid analgesics)**, or **any of the other ingredients** (see list of ingredients in Section 6).
- you **suffer from any illness causing breathing** difficulties. You may only be given Alfentanil if your breathing is helped by a machine called a ventilator.
- you are **taking** any of the antidepressant medicines known as m**onoamine oxidase inhibitors** (MAOIs) or **have taken them during the last two weeks**.

Alfentanil should not be given during labour or before the cord is clamped during Caesarean section.

Warnings and precautions

Talk to your doctor or nurse before you receive Alfentanil if you:
- have ever had a head injury - Alfentanil may influence the clinical signs of patients with head injuries.
- have ever had lung disease or other breathing difficulties.
- have ever had a liver or kidney disorder.
- have ever had a thyroid disorder.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Alfentanil to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- 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.

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, it is important that you consult your doctor.

Receiving this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop receiving this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop receiving the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Your doctor will carefully monitor the amount of Alfentanil you are given.

Special monitoring
- Alfentanil may make you breathe more slowly. Your breathing will be carefully monitored until it returns to normal
- Your blood pressure and heart rate will also be monitored

Babies, children and adolescents

Alfentanil can cause breathing difficulties, especially in babies and very young children. When babies and very young children are given Alfentanil:
- Their breathing will be carefully monitored during the operation and for some time afterwards.
- The doctor may give a medicine to relax the muscles and to prevent them becoming stiff.

Other medicines and Alfentanil

Concomitant use of Alfentanil and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

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.

However, if your doctor does prescribe Alfentanil together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines, including medicines you can get without a prescription. This is especially important with the following medicines as they may interact with your Alfentanil:
- Medicines for depression called 'monoamine oxidase inhibitors (MAOIs)', taken in the past two weeks
- Selective Serotonin Reuptake Inhibitors' (SSRIs) or 'Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)'

The effects of Alfentanil may last longer if you are taking:
- Cimetidine - for ulcers, stomach ache and heartburn
- Erythromycin - an antibiotic
- Diltiazem - for a heart problem

Talk to your doctor before receiving Alfentanil if you are taking any of these medicines.

The effects of Alfentanil or any of these medicines may be increased when they are taken together
- Other strong medicines for pain, for example 'opioid analgesics' such as morphine or codeine
- Medicines for high blood pressure or heart problems called 'beta-blockers'
- Medicines for putting you to sleep called 'anaesthetic agents'
- Medicines for anxiety or to help you sleep such as tranquillisers or sleeping pills
- Medicines that affect your central nervous system (CNS depressants) such as medicines for mental disorders
- Medicines for epilepsy such as clobazam, clonazepam or phenobarbital

Talk to your doctor before receiving Alfentanil if you are taking any of these medicines. They may have to change the amount of Alfentanil or the other medicines you are given.

Certain medicines may affect the way Alfentanil works
- Medicines for fungal infections called fluconazole, voriconazole, ketoconazole or itraconazole
- Medicines for HIV infection (called antiviral protease inhibitors) such as ritonavir, indinavir or saquinivir

Talk to your doctor before receiving Alfentanil if you are taking any of these medicines. They may have to change the amount of Alfentanil you are given.

Alfentanil with alcohol

Tell your doctor or nurse if you use alcohol regularly, because the effect of Alfentanil may be increased or last longer.

Pregnancy and breast-feeding

Do not take Alfentanil if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you receive Alfentanil during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Alfentanil is not recommended during childbirth as it crosses the placenta and can affect your baby's breathing.

You may still be able to have Alfentanil if your doctor thinks you need to.

Alfentanil may get into breast milk and will affect your baby. Do not breast-feed or use breast milk that has been expressed during 24 hours after having Alfentanil.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

After you have been given Alfentanil you must not drive or operate machinery for at least 24 hours.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Alfentanil contains sodium

This medicine contains:
- 7.1 mg (or 0.31 mmol) sodium (main component of cooking/table salt) per 2 ml ampoule, that is to say essentially 'sodium-free'.
- 35.4 mg (or 1.54 mmol) sodium (main component of cooking/table salt) per 10 ml ampoule. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.
- 177 mg (or 7.70 mmol) sodium (main component of cooking/table salt) per 50 ml vial. This is equivalent to 9% of the recommended maximum daily dietary intake of sodium for an adult.

The following information is intended for medical or healthcare professionals only:

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PREPARATION GUIDE FOR:

Alfentanil 500 micrograms/ml solution for injection

This is a summary of the information regarding the preparation, storage and administration of Alfentanil 500 micrograms/ml solution for injection.

It is important that you read the entire contents of this guide prior to the preparation of this medicinal product.

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Nature and content of container

Alfentanil 500 micrograms/ml is supplied as a clear and colourless solution for injection in clear glass ampoules (Ph Eur Type I, one point cut) containing 1 mg/2 ml or 5 mg/10 ml and in clear glass vials (Ph Eur Type I) containing 1 mg/2 ml, 5 mg/10 ml or 25 mg/50 ml.

Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in the following paragraph "Dilution instructions".

Dilution instructions

Dilutions of Alfentanil 500 micrograms/ml should be prepared under controlled and validated aseptic conditions.

Alfentanil 500 micrograms/ml solution for injection may be diluted with sodium chloride injection BP, glucose injection BP, or Ringer Lactate injection BP (Hartmann's solution) to a concentration of 25-80 micrograms/ml. Such dilutions are compatible with plastic bags and giving sets.

Chemical and physical in-use stability of the dilutions has been demonstrated for 48 hours. From the microbiological point of view, the dilutions should be used immediately.

Storage

No special precautions for storage.

The product should be used immediately after opening the container.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Any unused solution from opened ampoules or vials should be discarded.

Posology and method of administration

Method of administration

Alfentanil is administered intravenously by injection or infusion and should only be given by individuals trained in the administration of general anaesthetics and the management of the respiratory effects of potent opioids. Alfentanil 500 micrograms/ml should be used as bolus injections (short procedures) or bolus supplemented by increments or by infusion (long painful surgical procedures).

Pulse oximetry or some other means for measuring respiratory function is recommended. Visually inspect parenteral products for particulate matter and discoloration prior to administration.

3. HOW ALFENTANIL IS GIVEN TO YOU

Alfentanil will be given to you by specifically trained health care professionals and emergency equipment will be available. Alfentanil is given as an infusion into a vein, usually on the back of the hand or in the forearm.

Your prescriber should have discussed with you, how long the course of Alfentanil will last.

They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Dosage

The amount of Alfentanil you need depends on your age, bodyweight, fitness, your condition, the use of other drugs and the type of surgery and level of anaesthesia that is needed.

Obese patients may need a dose based on their ideal body weight.

In Adults

The usual recommended dosage is as follows:

	Starting dose	Additional doses
Breathing normally	500 micrograms (1 ml)	250 micrograms (0.5 ml)
Assisted breathing	30 - 50 micrograms/kg	15 micrograms/kg

In Neonates, Infants and Children

Your child will be given Alfentanil by a nurse or doctor. Your doctor will decide the correct dosage for your child and how and when the injection will be given.

If you have any further questions or concerns on the use of this medicine for your child ask the doctor or nurse giving the injection.

Elderly or ill patients

Less Alfentanil may be used in patients that are elderly or weak due to ill health.

If you have been given too much Alfentanil

It is unlikely that you will be given too much Alfentanil. This will be monitored during your operation.

If you stop being given Alfentanil

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Alfentanil can cause side effects, although not everybody gets them.

Occasionally, Alfentanil may cause allergic reactions such as rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue. Please inform your doctor or nurse **immediately** if one or more of these reactions occur.

The following side effects have been reported:

Very common (affects more than 1 in 10 people)

- feeling sick (nausea) or being sick (vomiting)

Common (affects fewer than 1 in 10 people)

- Slower or weaker breathing or your breathing may stop for a short period of time. If necessary, your breathing will be helped by a machine (ventilator)
- Muscle stiffness, which may involve your chest muscles
- Dizziness and fainting. These are signs of lowered blood pressure
- Raised blood pressure
- Feeling tired or sleepy
- Feeling cold or shivering
- Feeling excited or unusually carefree
- Feeling calm and relaxed
- Fast or slow heartbeat
- Blurred or double vision
- Pain where the injection was given
- Pain due to the procedure undertaken
- Unusual movements

Uncommon (affects fewer than 1 in 100 people):

- Choking caused by cramping (spasm) of the muscles in your throat
- Slower or weaker breathing returning
- Feeling sleepy or unresponsive
- Breathing faster possibly with flushing of the skin
- An irregular heartbeat
- Sweating or skin rash
- Headache
- Hiccups
- General body aches and pains
- Problems urinating (urinary retention)

Rare (affects fewer than 1 in 1,000 people)

- Difficulty in breathing, wheezing or shortness of breath
- Nose bleeds
- Itchy skin
- Feeling agitated
- Crying
- Vein pain
- Complications due to the procedure undertaken (including the insertion of a breathing tube)
- Complications due to anaesthesia

Not known:

- Breathing can stop completely, which may be fatal
- Heart attack
- Fits or seizures
- Loss of consciousness after your operation
- Pupils of the eye much smaller than normal
- Fever or high temperature
- Redness of the skin or rash
- Feeling disorientated
- Muscle twitches
- Cough
- Dependence and addiction (see section “How do I know if I am addicted?”).

Drug Withdrawal

When you stop receiving Alfentanil, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst receiving Alfentanil, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop receiving the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

Reporting of side effects

If you get any side effects, talk to your doctor or nurse: This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme - Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ALFENTANIL

Keep out of the sight and reach of children.

Your doctor and pharmacist are responsible for the correct storage, use and disposal of Alfentanil.

Do not use Alfentanil after the expiry date which is stated on the carton and label after “EXP.”. The expiry date refers to the last day of that month.

Do not use Alfentanil if you notice the solution is not clear, colourless and free of particles or if the container is damaged.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Alfentanil contains

The active substance is alfentanil hydrochloride.

1 ml of Alfentanil contains 543.8 micrograms alfentanil hydrochloride hydrate, equivalent to 500 micrograms alfentanil base.

The other ingredients are water for injections, sodium chloride and hydrochloric acid.

What Alfentanil looks like and contents of the pack

Alfentanil is a clear and colourless solution for injection.

Pack containing 5 or 10 clear glass ampoules containing 1 mg in 2 ml

Pack containing 5 or 10 clear glass ampoules containing 5 mg in 10 ml

Pack containing 5 or 10 clear glass vials containing 1 mg in 2 ml

Pack containing 5 or 10 clear glass vials containing 5 mg in 10 ml

Pack containing 1, 5 or 10 clear glass vials containing 25 mg in 50 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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Infuse i.v. slowly over 3 minutes. Injections rates of < 1 minute are associated with an increased incidence of hypotension.

Continuous infusions longer than 4 days have not been studied.

Alfentanil 500 micrograms/ml by the intravenous route can be administered to both adults and children.

Dosage in adults

The dosage of Alfentanil 500 micrograms/ml should be individualised according to age, bodyweight, physical status, underlying pathological condition, use of other drugs and type of surgery and anaesthesia.

Dosage in children

The wide variability in response to alfentanil makes it difficult to provide dosing recommendations for younger children. For older children a bolus dose of 10 to 20 micrograms/kg alfentanil for induction of anaesthesia (i.e. to supplement propofol or inhalation anaesthesia) or as an analgesic is considered appropriate. Supplemental boluses of 5 to 10 micrograms/kg alfentanil at appropriate intervals can be administered.

To maintain analgesia in children during surgery, an Alfentanil 500 micrograms/ml infusion rate of 0.5 to 2 micrograms/kg/min may be administered. The dose must be titrated up or down according to the needs of the individual patient. When combined with an intravenous anaesthetic agent the recommended dose is approximately 1 micrograms/kg/min.

There may be a higher risk of respiratory complications and muscle rigidity when alfentanil is administered to neonates and very young children.

Assisted ventilation equipment should be available for use in children of all ages, even for short procedures in spontaneously breathing children.

Dosage in elderly or debilitated patients

Elderly (>65 years of age) and debilitated patients may require lower or less frequent dosing owing to a longer half-life of alfentanil in this age group (dilution may be helpful).

In obese patients (more than 20 % above ideal total body weight), the dosage of alfentanil should be determined on the basis of lean body weight.

Patients with hepatic impairment: Dose should be modified depending on the clinical response and degree of hepatic impairment, however no quantitative recommendations are available.

In patients with hypothyroidism the dosage should be titrated with care and prolonged monitoring may be required.

For more information regarding recommended dose modifications please refer to the Summary of Product Characteristics.

Marketing Authorisation Holder

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