PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

hameln

Alfentanil 5 mg/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 receiving it suddenly.

The name of your medicine is Alfentanil 5 mg/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 to:
- prevent pain during painful operations
- prevent pain during brief painful procedures (suction through a breathing tube, physiotherapy etc.)
- prevent pain and depress breathing activity in artificially ventilated patients in intensive care
- help patients tolerate artificial breathing and the placement of an endotracheal (wind-pipe) tube

Artificially ventilated patients may remain awake if they have appropriate pain control.

This medicine has been prescribed to you. 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**, or **any of the other ingredients** (see list of ingredients in Section 6).
- you **suffer from any illness causing breathing difficulties and** your breathing **is not assisted during and/or after surgery**
- you are **taking** any of the antidepressant medicines known as **monoamine 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 receive 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 receiving 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.

Receiving 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.

Children

Alfentanil is not recommended for use in children in intensive care.

Elderly

The initial dose of Alfentanil should be appropriately reduced in elderly and debilitated patients.

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

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 2 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

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

Your doctor 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 saquinavir

Your doctor 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

Pregnancy

You should not be given 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 should not be used during childbirth as it can affect the baby's breathing.

Breast-feeding

You should not be given Alfentanil while you are breastfeeding as it passes into breast milk and will affect your baby.

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 receiving 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 received 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 receiving this medicine.

Alfentanil contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per each 5 mg dose, that is to say essentially 'sodium-free'.

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 injection 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 receiving 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.

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

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Alfentanil 5 mg/ml solution for injection

This is a summary of the information regarding the preparation, storage and administration of Alfentanil 5 mg/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 5 mg/ml is supplied as a clear and colourless solution for injection in clear glass ampoules (Ph Eur Type I, one point cut) containing 5 mg/1 ml. Original pack containing 5 or 10 ampoules of 1 ml each.

Incompatibilities

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

Dilution instructions

Alfentanil 5 mg/ml solution for injection should be diluted with sodium chloride intravenous infusion BP, glucose intravenous infusion BP, or compound sodium lactate intravenous infusion BP (Hartmann's solution). 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.

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

Alfentanil should be administered only by persons specifically trained in the use of intravenous and general anaesthetic agents and the management of respiratory effects of potent opioids. An opioid antagonist, resuscitative and intubation equipment and oxygen should be readily available. Because of the possibility of delayed respiratory depression, monitoring of the patient must continue well after surgery.

At the proposed doses, Alfentanil 5 mg/ml solution for injection has no sedative activity. Therefore supplementation with an appropriate hypnotic or sedative agent is recommended. Admixture is not advisable due to the need to individually titrate both agents.

Alfentanil should only be prescribed by physicians familiar with the use of potent opioids when given by continuous i.v. infusion.

Dosage

Adults

Once the patient has been intubated, mechanical ventilation can be initiated using the following dosage regimen:

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Leatus Code	xxxx
Date last revised:	11/07/2022
Last revised by:	J.Jones
Customer	hameln pharma ltd
Country	UK
Language:	English
Product:	Alfentanil 5mgml (Hemofarm)
Component:	Leaflet (Hemofarm)
Dimensions:	296 x 420 mm
Software:	Adobe Illustrator CC
Font(s):	Arial regular, bold
Colour(s):	Black
Signature:	

ID Code = xxxxxxxx — Diecut

- The recommended starting dose for mechanically ventilated adult patients is 2 mg per hour of Alfentanil. For a 70 kg patient, this is about 30 micrograms per kilogram body weight per hour.
- Adolescents and young adults will require higher than average doses.
- Elderly and those patients with liver disease and hypothyroidism (under-active thyroid gland) will require lower doses.
- Obese patients may need a dose based on their ideal body weight.

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 / while you are in intensive care.

If you stop being given Alfentanil

Do not suddenly stop receiving this medicine. If you want to stop receiving 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 receiving this medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Alfentanil can cause side effects, although not everybody gets them. Your doctor will monitor these effects during your operation / while you are in intensive care.

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), 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. Your breathing will be helped by a machine (ventilator) until you are able to breathe by yourself
- 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
- Muscle twitching or stiffness (which may involve your chest muscles)
- 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)
- Hiccups
- Choking caused by cramping (spasm) of the muscles in your throat
- Headache
- Sweating or skin rash
- An irregular heartbeat
- Slower or weaker breathing returning
- Problems urinating (urinary retention)
- Feeling sleepy (somnolence)
- Unconsciousness
- Pain

Rare (affects fewer than 1 in 1,000 people)
- Difficulty 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:
- Heart attack
- Fits or seizures
- Pupils of the eye much smaller than normal
- Loss of consciousness after your operation
- Fever or high temperature
- Breathing can stop completely, which may be fatal
- Cough
- Feeling disorientated
- Skin redness or rash
- 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 receive the medicine for longer than advised by your prescriber
- You feel you need to receive 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 receiving 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, pharmacist 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 5.44 mg alfentanil hydrochloride hydrate, equivalent to 5 mg 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 of 1 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Nexus, Gloucester Business Park
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Manufacturer

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HBM Pharma s.r.o.
Sklabinská 30
03680 Martin, Slovakia

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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xxxx/28/22

The recommended initial infusion rate for mechanically ventilated adult patients is 2 mg per hour (equivalent to 0.4 ml per hour) of undiluted Alfentanil 5 mg/ml solution for injection. For a 70 kg patient, this corresponds to approximately 30 micrograms per kilogram per hour.

More rapid control may initially be gained by using a loading dose. For example, a dose of 5 mg may be given in divided doses over a period of 10 minutes, during which time careful monitoring of blood pressure and heart rate should be performed. If hypotension or bradycardia occurs, the rate of administration should be reduced accordingly and other appropriate measures instituted.

The dose to produce the desired effects should then be individually determined and reassessed regularly to ensure that the optimum dose is being used.

In clinical trials, patient requirements have generally been met with doses of 0.5 to 10 mg alfentanil per hour.

Additional bolus doses of 0.5 - 1.0 mg alfentanil may be given to provide analgesia during short painful procedures.

The maximum recommended duration of treatment with alfentanil infusions is 4 days.

Paediatric patients

Alfentanil 5 mg/ml solution for injection is not recommended for use in children in intensive care. Currently available data are described in the Summary of Product Characteristics but no recommendation on a posology can be made.

Elderly and debilitated patients

The elderly (>65 years of age) and those patients with liver impairment and hypothyroidism will require lower doses. Obese patients may require a dose based on their lean body mass.

Present data suggest that clearance of alfentanil is unaltered in renal failure. However there is an increased free fraction and hence dosage requirements may be less than in the patient with normal renal function.

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

Method of administration

For intravenous infusion.

Marketing Authorisation Holder

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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