In this leaflet:
1. What is ALFENTANIL and what is it used for?
2. Before you are given ALFENTANIL
3. How you will be given ALFENTANIL
4. Possible side effects
5. Storing ALFENTANIL
6. Further information

1. What is ALFENTANIL and what is it used for?

What is ALFENTANIL?
ALFENTANIL 5 mg/ml, Solution for Injection is a potent and short-acting painkiller. It belongs to a group of medicines known as opioid analgesics which relieve or prevent pain.

What is ALFENTANIL used for?
ALFENTANIL is used to control pain and breathing when using an artificial breathing machine in intensive care.

ALFENTANIL 5 mg/ml, Solution for Injection will be diluted and given as an infusion (a 'drip') into a vein.

2. Before you are given ALFENTANIL

Always inform your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

Always tell your doctor about any medicines (either prescribed by a doctor or that you have bought) which you have taken recently or are taking now.

Do not use ALFENTANIL:
- if you are taking, or have recently been taking (within the last two weeks), any of the antidepressant medicines known as monoamine oxidase inhibitors (MAOIs), including moclobemide.
- if you think that you may have had an allergic or any other type of reaction to ALFENTANIL or a similar medicine in the past. An allergic reaction may be recognized as a rash, itching, swollen face or lips, or shortness of breath.
- if you are pregnant or think that you are pregnant.

If any of the above applies to you, tell the doctor.

Warnings
Medicines like ALFENTANIL 5 mg/ml, Solution for Injection may cause a drop in blood pressure and breathing rate. These effects are usually short-lived. It may also cause the heart to beat more slowly.

Particular care has to be taken following treatment with other medicines which have similar effects. Blood pressure and heart rate are therefore monitored during administration of ALFENTANIL and any unwanted effects of this nature can be reversed with other medicines. Rarely, the rhythm of the heart may be altered and this will be treated if it occurs.

The doctor who will be giving ALFENTANIL 5 mg/ml, Solution for Injection will be aware of the possibility of all these unwanted effects and will take steps to avoid them.
Special Precautions
Your doctor will take special precautions when giving you ALFENTANIL if any of the points listed below applies to you:

- The dose of ALFENTANIL 5 mg/ml, Solution for Injection is normally reduced in elderly patients, and those with some thyroid problems or liver disease.
- Your dose will be carefully monitored if you have a history of lung disease, alcoholism, kidney problems or if you have been on long term opioid therapy.
- ALFENTANIL can make the muscles stiff. Your doctor will take measures to avoid this happening.
- As with all strong opioid painkillers, good pain relief is accompanied by a lowering of the breathing rate. This may last into the recovery period or occur again during this time. This effect may be increased if you have recently used similar medicines for pain relief. Your breathing will therefore be carefully monitored until it returns to normal.

Taking other medicines
Always tell your doctor if you are taking any other medicines because taking some medicines together can be harmful. Remember that the doctor at the hospital may not have been informed if you have recently begun a course of treatment for another illness.

Some medicines may affect the length of time it takes for the effects of ALFENTANIL to wear off:
- cimetidine, a medicine for ulcers, stomach-ache and heartburn
- erythromycin, an antibiotic
- diltiazem, a medicine used for a certain type of heart disorder.

Some medicines will have some of the same effects as ALFENTANIL. When one or more of these medicines is used at the same time as ALFENTANIL, the effects of either may be increased.
- beta-blockers (used to treat high blood pressure and disorders of heart rhythm)
- anaesthetic agents
- drugs which depress the central nervous system (such as tranquillisers and sleeping pills)
- benzodiazepines e.g. clobazam, clonazepam (used to treat epilepsy)
- barbiturates e.g. phenobarbitone
- other strong opioid painkillers.

It may also be necessary to adjust the dose of ALFENTANIL 5 mg/ml, Solution for Injection if you are taking the following:
- certain medicines for fungal infections, e.g. fluconazole, ketoconazole and itraconazole;
- certain medicines called antiviral protease inhibitors, e.g. ritonavir.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Pregnancy and breast feeding
If you are pregnant, or think you may be, you should inform your doctor. He/she will decide whether or not you should be given ALFENTANIL.

ALFENTANIL may get into breast milk. It is therefore recommended that you should not breast feed for 24 hours after treatment.

Driving and using machines
You should not drive or operate machinery for 24 hours after being given ALFENTANIL as you may be less alert than usual.

3. How you will be given ALFENTANIL
Your doctor will decide how much ALFENTANIL 5 mg/ml, Solution for Injection you need. This will depend, for example, on the type of surgery, your body weight, age and general health.

ALFENTANIL 5 mg/ml, Solution for Injection should be mixed with sodium chloride injection, dextrose injection or compound sodium lactate injection (Hartmann’s solution). These dilutions should be used within 24 hours of preparation.

The usual recommended dosage is as follows:

Adults:
Your initial dose will be 2 mg per hour. Sometimes a higher initial dose (for example 5 mg) is given over a period of 10 minutes to achieve more rapid control.

Adolescents and young adults will be given higher than the average adult dose.

Elderly:
The above amounts of ALFENTANIL 5 mg/ml, Solution for Injection will be reduced.

Patients with liver problems and hypothyroidism (underactive thyroid) will also need their dose of ALFENTANIL to be reduced from the normal adult dosage.
Children:
ALFENTANIL 5 mg/ml Solution for Injection is not usually used to treat children in intensive care.

The usual maximum treatment time with ALFENTANIL infusions is 4 days.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, using Alfentanil can cause side-effects, although not everybody gets them.

To give you an idea of how many patients might get side effects, they have been listed as very common, common, uncommon, rare and very rare. These mean the following:

<table>
<thead>
<tr>
<th>Very common</th>
<th>More than 1 in 10 people.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common</td>
<td>up to 1 in 10 people.</td>
</tr>
<tr>
<td>Uncommon</td>
<td>up to 1 in 100 people.</td>
</tr>
<tr>
<td>Rare</td>
<td>up to 1 in 1,000 people.</td>
</tr>
<tr>
<td>Very rare</td>
<td>fewer than 1 in 10,000 people.</td>
</tr>
</tbody>
</table>

These are the side effects we know about for ALFENTANIL 5 mg/ml, Solution for Injection:

- **Very common:** Feeling or being sick.
- **Common:** Low blood pressure (hypotension); high blood pressure (hypertension), muscle stiffness, twitching, dizziness, slow or fast heart beat, feeling sleepy, stopping breathing temporarily, lowered breathing rate.
- **Uncommon:** Pain at the site of the injection, shivering, allergic reaction (such as difficulty in breathing, skin rash or itching, or swollen face), headache, irregular heart beat, feeling disorientated, agitation, feeling ‘high’ (euphoria), cough, continued lowered breathing rate, tightness of the throat, hiccup, itching of the skin, sweating, blurred or ‘double’ vision.

If you think your medicine has affected you in any other way, you should tell the doctor.

See also Section 2, Before you are given ALFENTANIL 5 mg/ml, Solution for Injection, above.

5. Storing ALFENTANIL
Keep out of the reach and sight of children.

You must not be given ALFENTANIL 5 mg/ml, Solution for Injection after the expiry date (month and year) printed after “EXP” on the carton. The expiry date refers to the last day of that month.

Dilutions made with ALFENTANIL 5 mg/ml, Solution for Injection must be used within 24 hours of preparation.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

**What ALFENTANIL contains:**
The name of your medicine is ALFENTANIL 5 mg/ml, Solution for Injection and its active ingredient is ALFENTANIL. Each millilitre contains 5 milligrams of ALFENTANIL (as the hydrochloride).

The solution for injection also contains sodium chloride, water for injections, sodium hydroxide and hydrochloric acid.

This medicinal product contains less than 1 mmol sodium (23 mg) per 5 mg dose, i.e. essentially 'sodium-free'.

**What ALFENTANIL looks like and contents of the pack:**
It is a solution for injection which comes in 1 millilitre (ml) clear glass ampoules. It is a clear colourless solution.

ALFENTANIL 5 mg/ml, Solution for Injection is supplied in packs of 10 x 1 ml ampoules.

**Marketing authorisation holder:**
Auden Mckenzie (Pharma Division) Ltd.
Mckenzie House
Bury Street
Ruislip
Middlesex
HA4 7TL
UK
Manufacturer:
SNS Pharmaceuticals Ltd
30 Stadium Business Centre
North End Road
Middlesex
HA9 0HF
UK

This leaflet was last approved in February 2010.

For information in large print, on tape, on CD or in Braille, phone 01895 627 420.

ALFENTANIL Intensive Care 5mg/ml, Solution for Injection
PL 17507/0037
1. NAME OF THE MEDICINAL PRODUCT

Alfentanil 5 mg/ml, Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Alfentanil solution for injection contains 5 mg alfentanil (as hydrochloride) per ml.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Alfentanil is a potent opioid analgesic with a very rapid onset of action. It is indicated for analgesia and suppression of respiratory activity in mechanically ventilated patients on intensive care and to provide analgesic cover for painful manoeuvres. It will aid compliance with mechanical ventilation, and tolerance of the endotracheal tube. Intravenous bolus doses of Alfentanil 5 mg/ml (0.5 mg/ml) may be used to provide additional pain relief during brief painful procedures such as physiotherapy, endotracheal suction, etc. Despite being mechanically ventilated, patients may be awake in the presence of adequate analgesia.

At the proposed doses, Alfentanil 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 given by infusion should only be given in areas where facilities are available to deal with respiratory depression and where continuous monitoring is performed. Alfentanil should only be prescribed by physicians familiar with the use of potent opioids when given by continuous IV infusion.

4.2 Posology and method of administration

For intravenous infusions.

Dosage

Alfentanil 5 mg/ml 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. These dilutions should be used within 24 hours of preparation.

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

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). 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 elderly and those patients with liver impairment and hypothyroidism will require lower doses. Obese patients may require a dose based on their lean body mass.

Adolescents and young adults will require higher than average doses. There is little experience of use of alfentanil to treat children in intensive care.

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

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.

4.3 Contraindications

Known intolerance of alfentanil or other morphinomimetics. Pregnancy, and concurrent administration with monoamine oxidase inhibitors.

4.4 Special warnings and special precautions for use

**Warnings:**

Following administration of Alfentanil, a fall in blood pressure may occur. The magnitude of this effect may be exaggerated in the hypovolaemic patient or in the presence of concomitant sedative medication. Appropriate measures to maintain a stable arterial pressure should be taken.

Like other opioids, alfentanil may cause bradycardia, an effect which may be marked and rapid in onset but which can be antagonised by atropine.

Particular care must be taken following treatment with drugs which may depress the heart or increase vagal tone, such as anaesthetic agents or beta-blockers since they may predispose to bradycardia or hypotension. Heart rate and blood pressure should therefore be monitored carefully. If hypotension or bradycardia occurs, the rate of administration of alfentanil should be reduced and other appropriate measures instituted. Asystole following bradycardia has been reported on very rare occasions in non-atropinised patients. Therefore it is advisable to be prepared to administer an anticholinergic drug.

Care must be taken if the patient has received monoamine oxidase inhibitors within the previous 2 weeks.

Significant respiratory depression and loss of consciousness will occur following administration of alfentanil in doses in excess of 1 mg and is dose-related. If necessary for assessment purposes, naloxone or other specific antagonists may be administered to reverse the opioid respiratory depression and other pharmacological effects of alfentanil. More than one dose of naloxone may be required in view of its short half life.

Muscle rigidity (morphine-like effect) may occur, in which case neuromuscular blocking drugs may be helpful.

**Precautions:**

It is wise to reduce the dosage in the elderly and debilitated patient. In hypothyroidism, pulmonary disease, decreased respiratory reserve, alcoholism and liver or renal impairment the dosage should be titrated with care and prolonged monitoring may be required.

Patients on chronic opioid therapy or with a history of opioid abuse may require higher doses.

Non-epileptic (myo)clonic movements can occur.

As with all potent opioids, profound analgesia is accompanied by marked respiratory depression, which may persist into or recur in the early post infusion period. Care should therefore be taken throughout the weaning period and adequate spontaneous respiration should be established and maintained in the absence of stimulation or ventilatory support. Following cessation of the infusion, the patient should be closely observed for at least 6 hours. Prior use of opioid medication may enhance or prolong the respiratory depressant effects of alfentanil.

The use of rapid bolus injections of opioids should be avoided in patients with compromised intracerebral compliance; in such patients a transient decrease in the mean arterial pressure has occasionally been accompanied by a transient reduction of the cerebral perfusion pressure.

This medicinal product contains less than 1 mmol sodium (23 mg) per 5 mg dose, i.e. essentially 'sodium-free'.
4.5 Interaction with other medicinal products and other forms of interaction

Alfentanil is metabolised mainly via the human cytochrome P450 3A4 enzyme. Available human pharmacokinetic data indicate that the metabolism of alfentanil may be inhibited by fluconazole, erythromycin, diltiazem and cimetidine (known cytochrome P450 3A4 enzyme inhibitors). In vitro data suggest that other potent cytochrome P450 3A4 enzyme inhibitors (e.g. ketoconazole, itraconazole, ritonavir) may also inhibit the metabolism of alfentanil. This could increase the risk of prolonged or delayed respiratory depression. The concomitant use of such drugs requires special patient care and observation; in particular, it may be necessary to lower the dose of Alfentanil.

Treatment with drugs which may depress the heart or increase vagal tone, such as beta-blockers and anaesthetic agents, may predispose to bradycardia or hypotension. Bradycardia and possibly asystole can occur when Alfentanil 5 mg/ml is combined with non-vagolytic muscle relaxants.

Prior use of opioid premedication, barbiturates, benzodiazepines, neuroleptics, halocarbon gases and other non-selective CNS depressants may enhance or prolong the respiratory depressant effects of alfentanil.

If other narcotic or CNS depressant drugs are used concurrently with alfentanil, the effects of the drugs can be expected to be additive. When patients have received such drugs, the dose of alfentanil required will be less than usual. Likewise, following the administration of alfentanil, the dose of other CNS-depressant drugs should be reduced.

4.6 Pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy. Although no teratogenic or acute embryotoxic effects have been observed in animal experiments, the potential risk for humans is unknown.

Alfentanil should not be used in pregnancy unless clearly necessary. I.V. administration during childbirth (including Caesarean section) is not recommended, because alfentanil crosses the placenta and because the foetal respiratory centre is particularly sensitive to opiates. If, however, alfentanil is administered, an antidote should always be at hand for the child.

Alfentanil may appear in breast milk. It is therefore recommended that breast feeding is not initiated within 24 hours of treatment.

4.7 Effects on ability to drive and use machines

Where early discharge is envisaged, patients should be advised not to drive or operate machinery for the 24 hours following administration.

4.8 Undesirable effects

The most frequently reported ADRs (incidence ≥ 10%) are: nausea and vomiting. Undesirable effects listed below in Table 1 have been reported in a clinical trial and/or from spontaneous reports from post-marketing experience. The following terms and frequencies are applied: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1000 to < 1/100), rare (≥ 1/10,000 to < 1/1000), very rare (< 1/10,000), and not known (frequency cannot be estimated from the available data). Adverse drug reactions from spontaneous reports during worldwide postmarketing experience with Alfentanil that met threshold criteria are included. Unlike for clinical trials, precise frequencies cannot be provided for spontaneous reports. The frequency for these reports is therefore classified as 'not known'.

Adverse drug reactions from spontaneous reports during worldwide postmarketing experience with Alfentanil that met threshold criteria are included. Unlike for clinical trials, precise frequencies cannot be provided for spontaneous reports. The frequency for these reports is therefore classified as 'not known'.
### Table 1: Adverse drug reactions reported in clinical trials and/or postmarketing

<table>
<thead>
<tr>
<th>Body System/Organ Class</th>
<th>Clinical trials</th>
<th>Spontaneous Reports&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immune system disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Allergic reactions (such as anaphylaxis, bronchospasm, urticaria)</td>
<td></td>
</tr>
<tr>
<td><strong>Psychiatric Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common</td>
<td>Somnolence</td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Disorientation, Agitation, Euphoria</td>
<td></td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common</td>
<td>Muscle rigidity (may also involve thoracic muscles) Myoclonic movements, Dizziness</td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Headache</td>
<td></td>
</tr>
<tr>
<td>Not Known</td>
<td>Loss of consciousness (Postoperative period), Convulsion</td>
<td></td>
</tr>
<tr>
<td><strong>Eye disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Blurred/double vision</td>
<td></td>
</tr>
<tr>
<td>Not Known</td>
<td>Miosis</td>
<td></td>
</tr>
<tr>
<td><strong>Cardiac disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common</td>
<td>Bradycardia, Tachycardia</td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Arrhythmia</td>
<td></td>
</tr>
<tr>
<td>Not Known</td>
<td>Cardiac arrest</td>
<td></td>
</tr>
<tr>
<td><strong>Vascular Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common</td>
<td>Hypotension, Hypertension</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory, thoracic, and mediastinal disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common</td>
<td>Apnoea, Respiratory depression</td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Cough, Recurrence of respiratory depression, Laryngospasm, Hiccup</td>
<td></td>
</tr>
<tr>
<td>Not Known</td>
<td>Respiratory arrest (including fatal outcome)</td>
<td></td>
</tr>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very common</td>
<td>Nausea, Vomiting</td>
<td></td>
</tr>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Pruritis, Sweating</td>
<td></td>
</tr>
<tr>
<td><strong>General disorders and administration site conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>Injection site pain, Shivering</td>
<td></td>
</tr>
<tr>
<td>Not Known</td>
<td>Pyrexia</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>: Listed are only those adverse drug reactions that were not identified in clinical trials
4.9 Overdose

The manifestations of alfentanil overdose are generally an extension of its pharmacological action, which include the following:

**Action:**

- **Bradycardia:** Anticholinergics such as atropine or glycopyrrolate;
- **Hypoventilation or apnoea:** $O_2$ administration, assisted or controlled respiration and an opioid antagonist may be required;
- **Muscle rigidity:** Intravenous neuromuscular blocking agent may be given.

If hypotension is severe or persists, the possibility of hypovolaemia should be considered and controlled with appropriate parenteral fluid administration.

The suggested treatments given above do not preclude the use of other clinically indicated counter measures.

Body temperature and adequate fluid intake should be maintained and the patient observed for 24 hours. A specific narcotic antagonist (e.g. naloxone) should be available to treat respiratory depression.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

In man, alfentanil at therapeutic doses has no detrimental effects on myocardial performance. The cardiovascular stability is remarkable both in healthy and poor-risk patients. The only changes seen in blood pressure and heart rate were transient, slight decreases occurring immediately after induction. The incidence and degree of respiratory depression is less and of shorter duration after alfentanil than with fentanyl. Like other narcotic analgesics, alfentanil increases the amplitude of the EEG and reduces its frequency. Alfentanil reduces intraocular pressure by about 45%. It blocks increases in plasma cortisol and in plasma antidiuretic and growth hormones throughout surgery, and prevents increases in plasma catecholamines up to, but not during or after, cardiopulmonary bypass in patients undergoing open heart surgery.

5.2 Pharmacokinetic properties

After bolus injections ranging from 2.4 to 125 µg/kg, plasma levels in man decay triexponentially with a terminal half life of approx. 90 minutes. Total distribution volume varies from 0.4 to 1.0 l/kg, indicating a limited distribution of alfentanil to the tissues. Plasma clearance, varying from 3.3 to 8.3 ml/kg/min represents approximately one third of liver plasma flow indicating that elimination of alfentanil is not flow dependent. Since only 0.4% of the dose is excreted with the urine as unchanged drug, elimination of alfentanil occurs mainly by metabolism.

These main parameters in patients undergoing surgery are similar to those in healthy volunteers. Only when the drug was given as the sole anaesthetic in a continuous high infusion over about 5 hours was the clearance of alfentanil reduced resulting in a plasma half-life of about 200 minutes, the distribution volume not being markedly changed.

Plasma protein binding of alfentanil is 92%, mainly due to a strong binding to the ‘acute phase’ $\alpha_1$-acid-glycoprotein. It is not bound to the blood cells. Pharmacokinetics were comparable in rats, dogs and man. In children, alfentanil has been shown to have a much shorter half-life than adults, whereas the elderly show a longer half-life for alfentanil, after IV bolus doses.

5.3 Preclinical safety data

Preclinical effects observed were only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium chloride
- Water for injections
- Hydrochloric acid*  
- Sodium hydroxide*  
* for occasional pH adjustment only
6.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life
24 months (unopened).
24 hours (dilutions).

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
Type I Ph Eur clear glass ampoules containing 1 ml.
10 ampoules per carton.

6.6 Special precautions for disposal and other handling
If desired, Alfentanil Solution for Injection can be mixed with sodium chloride injection BP, dextrose injection BP or compound sodium lactate injection BP (Hartmann’s solution). Such dilutions are compatible with plastic bags and giving sets. These dilutions should be used within 24 hours of preparation.

7. MARKETING AUTHORISATION HOLDER
Auden McKenzie (Pharma Division) Ltd
Mckenzie House
Bury Street
Ruislip
Middlesex
HA4 7TL

8. MARKETING AUTHORISATION NUMBER(S)
PL17507/0037

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT
Legal category POM