NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Alfentanil 1 mg/2 mL MEDICIANZ
Alfentanil 5 mg/10 mL MEDICIANZ

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Alfentanil solution for injection contains 0.544 mg/mL of alfentanil hydrochloride, equivalent to 0.5 mg/mL of alfentanil base.

It is available as a sterile solution of alfentanil hydrochloride equivalent to 0.5 mg/mL alfentanil with 9.0 mg sodium chloride in water for injection to 1 mL.

Each 2 mL ampoule contains 1.0 mg of alfentanil (as hydrochloride).

Each 10 mL ampoule contains 5.0 mg of alfentanil (as hydrochloride).

Excipient(s) with known effect: sodium chloride 9.0 mg/mL

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Solution for injection

Medicianz Alfentanil injection is a clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Alfentanil injection is indicated in adults and children aged above one year for use as:

• an opioid analgesic in general or regional anaesthesia for both short (bolus injections) and long (bolus, supplemented by increments or by continuous infusion) surgical procedures.

• an anaesthetic induction agent.

Due to its rapid and short-lasting action, Alfentanil injection is particularly suited as an opioid analgesic for short procedures and outpatient surgery. It is also useful as an analgesic supplement for procedures of medium and long duration, since periods of very painful stimuli can easily be overcome by small increments of Alfentanil injection or by adapting its infusion rate.

4.2 Dose and method of administration

Alfentanil injection should be administered intravenously. Other routes of administration have not been evaluated.

The dosage of Alfentanil injection should be individualised according to age, body weight, physical status, underlying pathological condition, use of other medicines, type of anaesthesia and type and duration of the surgical procedure. As a general principle, the lowest effective dose should be used.

To avoid bradycardia, a small intravenous dose of an anti-cholinergic agent (e.g. atropine), be administered just before induction may be administered. Droperidol may be given to prevent nausea

and vomiting. However, it is preferable not to administer droperidol to outpatients since it may lengthen their recovery period.

Use as an induction agent

An intravenous bolus dose of ≥ 120 micrograms/kg (17 mL/70 kg) of Alfentanil injection will induce hypnosis and analgesia while maintaining good cardiovascular stability in patients with adequate muscle relaxation.

For short procedures and use in outpatients

Small doses of Alfentanil injection are suitable for minor, short but painful surgical procedures and for outpatients, provided good monitoring equipment is available.

An intravenous bolus dose of 7 to 15 micrograms/kg (1 to 2 mL/70 kg) will suffice for procedures lasting less than 10 minutes. Should the duration of the procedure exceed 10 minutes, further increments of 7 to 15 micrograms/kg (1 to 2 mL/70 kg) should be given every 10 to 15 minutes or as required.

Spontaneous respiration may be maintained in most instances with a dose of 7 micrograms/kg (1 mL/70 kg) or less, slowly injected. Suggested increments with this technique are 3.5 micrograms/kg (0.5 mL/70 kg).

It is preferable not to administer droperidol or benzodiazepines to outpatients as these medicines may lengthen the recovery period (see Section 4.5 Interactions with other medicines and other forms of interaction). In outpatients, the use of an anticholinergic agent, a short-acting induction hypnotic, Alfentanil injection and N2O/O2 is a preferred technique.

When post-operative nausea occurs, it is of relatively short duration and easily controlled by conventional measures.

For procedures of medium duration

The initial intravenous bolus dose should be adapted to the expected duration of the surgical procedure as follows:

Duration of the Procedure (minutes)	Alfentanil injection I.V. bolus dose	
	micrograms/kg	mL/70 kg
10-30	20-40	3-6
30-60	40-80	6-12
> 60	80-150	12-20

Continuous infusion is preferred for procedures of more than 60 minutes duration.

When surgery is prolonged or more traumatic, analgesia can be maintained by either of the following:

- increments of 15 micrograms/kg (2 mL/70 kg) of Alfentanil injection when required. To avoid postoperative respiratory depression, the last dose of Alfentanil injection should not be administered within the last 10 minutes of surgery, or
- infusion of Alfentanil injection at a rate of 1 micrograms/kg/minute (0.14 mL/70 kg/minute) until 5 to 10 minutes before the completion of surgery.

Periods of very painful stimuli can be easily overcome by small increments of Alfentanil injection or by temporarily increasing the infusion rate. When Alfentanil injection is used without N2O/O2 or other

inhalation anaesthetic agents, the maintenance dose of Alfentanil injection should be increased.

Alfentanil injection may be administered as an infusion for more prolonged procedures with the following infusion solutions:

- 0.9% sodium chloride injection
- 5.0% glucose injection
- compound sodium lactate intravenous injection (Ringer LactateInjection).

WARNING: The prepared infusion should commence as soon as possible after its preparation and within 24 hours of preparation. Any storage of the prepared solution should be at 2 - 8°C. Alfentanil injection must not be mixed with any products other than those listed above.

For long procedures

Alfentanil injection may be used as the analgesic component of anaesthesia for long lasting surgical procedures, especially when rapid extubation is indicated. Optimum analgesia and stable autonomic condition are maintained through an individually adapted initial intravenous dose, and by adjusting the infusion rate to the severity of the surgical stimuli and the reactions of patients.

Special populations

Paediatric Use

The safety of Alfentanil injection in children younger than one year has not been established. The usual children's dose of Alfentanil injection is identical to that used in adults, however, some cases may require a higher or more frequent dosing due to Alfentanil injection having a shorter half-life in children.

Elderly and debilitated patients

The initial dose should be appropriately reduced in the elderly (>65 years of age) and in debilitated patients. The effect of the initial dose should be taken into account in determining supplemental doses.

Product is for single use in one patient only. Discard any residue.

4.3 Contraindications

Alfentanil injection is contraindicated in those with a known intolerance or sensitivity to alfentanil, or to other opioid analgesics.

4.4 Special warnings and precautions for use

Alfentanil injection should be administered only by persons specifically trained in the use of intravenous and general anaesthetic agents, and in the management of respiratory effects of potent opioids.

An opioid antagonist, oxygen, and resuscitative and intubation equipment should be readily available. Due to the possibility of delayed respiratory depression, monitoring of the patient must continue until well after surgery in an approved recovery facility.

Respiratory Depression

As with other potent opioids, profound analgesia is accompanied by marked respiratory depression and loss of consciousness, which can persist or recur in the post-operative period. Respiratory

depression is dose related and can be reversed by specific opioid antagonists such as naloxone. Naloxone administration may need to be repeated because the respiratory depression may last longer than the duration of action of the opioid antagonist. Recovery room staff should be aware that marked respiratory depression has been reported as occurring after periods of up to several hours after the patient has been perceived to be alert, conversing coherently, and with normal respiration. For this reason, patients should remain under appropriate surveillance. Resuscitation equipment and opioid antagonists should be readily available. Hyperventilation during anaesthesia may alter the patient's responses to CO2, thus affecting respiration postoperatively.

Risk from concomitant use of Central Nervous System (CNS) depressants, especially benzodiazepines or related drugs

Concomitant use of Alfentanil injection and CNS depressants especially benzodiazepines or related drugs in spontaneous breathing patients, may increase the risk of profound sedation, respiratory depression, coma and death. If a decision is made to administer Alfentanil injection concomitantly with a CNS depressant, especially a benzodiazepine or a related drug, the lowest effective dose of both drugs should be administered, for the shortest period of concomitant use. Patients should be carefully monitored for signs and symptoms of respiratory depression and profound sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see Section 4.5 Interactions with other medicines and other forms of interaction).

Muscle Rigidity

Induction of muscle rigidity, which may also involve the thoracic muscles can occur, but can be avoided by the following measures:

- slow intravenous injection, especially when higher doses are indicated
- premedication with benzodiazepines
- administration of muscle relaxants prior to a dose of Alfentanil injection.

Non-epileptic (myo)clonic movements can occur.

Cardiac Effects

Bradycardia and possibly cardiac arrest can occur if the patient has received an insufficient amount of anticholinergic agent, or when Alfentanil injection is combined with non-vagolytic muscle relaxants. Bradycardia can be treated with atropine.

Alfentanil injection may induce hypotension, especially in hypovolaemic patients. Appropriate measures to maintain a stable arterial pressure should be taken.

Use in Patients with Compromised Intracerebral Compliance

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

Use in the Elderly

It is recommended that the dose of Alfentanil injection be reduced in the elderly, because of reduced clearance. The dosage should be individualised based on clinical response.

Use in Hepatic or Renal Impairment

It is recommended that the dose of Alfentanil injection be reduced in those patients with chronic liver or kidney disease, because of decreased plasma protein concentrations and reduced clearance. Due

to the variable pharmacokinetics and pharmacodynamics, the dosage should be titrated individually and adjusted on the basis of the clinical response.

Use in Hypothyroidism

It is recommended that the dose of Alfentanil injection be reduced in those patients with hypothyroidism, because of reduced clearance. The dosage should be individualised based on clinical response.

Others

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

Alfentanil injection should be titrated with caution in those with any of the following conditions: pulmonary disease, decreased respiratory reserve and alcoholism. Such patients also require prolonged post-operative monitoring.

As is the case with any opioid analgesic, Alfentanil injection should not be used in patients who may be particularly susceptible to respiratory depression such as comatose patients who may have head injury or brain tumour.

4.5 Interaction with other medicines and other forms of interaction

Anaesthetic Agents

As with other opioids, the respiratory depressant and cardiovascular depressant effects of Alfentanil injection may be potentiated by halogenated inhalation agents such as propofol. When patients have received such agents, the dose of Alfentanil injection required will be less than usual.

Central Nervous System (CNS) depressants

Medicines such as barbiturates, benzodiazepines or related drugs, phenothiazine derivatives, neuroleptics, general anaesthetics, and other non-selective CNS depressants (e.g. alcohol) may potentiate the respiratory depressant and cardiovascular depressant effects of opioids. When patients have received such CNS depressants, the dose of Alfentanil injection required will be less than usual. Concomitant use with Alfentanil injection in spontaneously breathing patients may increase the risk of respiratory depression, profound sedation, coma, and death (see Section 4.4 Special warnings and precautions for use).

Likewise, Following the administration of Alfentanil injection, the dose of other CNS-depressant medicines should be reduced. This is particularly important after surgery, because profound analgesia is accompanied by marked respiratory depression, which can persist or recur in the postoperative period. Administration of a CNS depressant, such as a benzodiazepine or related drugs, during this period may disproportionally increase the risk for respiratory depression (see Section 4.4 Special warnings and precautions for use).

Cytochrome P450 3A4 (CYP3A4) inhibitors

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

Monoamine Oxidase Inhibitors (MAOI)

As monoamine oxidase inhibitors have been reported to potentiate the effects of opioid analgesics, the use of Alfentanil injection in patients who have received MAO inhibitors within two weeks should be avoided.

Serotonergic medicines

Coadministration of alfentanil with a serotonergic agent, such as Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin Norepinephrine Reuptake Inhibitors (SNRIs), or Monoamine Oxidase Inhibitors (MAOIs), may increase the risk of serotonin syndrome, a potentially life-threatening condition.

Effect of Alfentanil on the Metabolism of Other Medicines

In combination with Alfentanil injection, the blood concentrations of propofol are 17% higher than in the absence of Alfentanil injection. The concomitant use of alfentanil and propofol may require a lower dose of Alfentanil injection.

4.6 Fertility, pregnancy and lactation

Pregnancy

The intravenous use of opioid analgesics during labour (including caesarean section) can cause respiratory depression in the newborn infant since Alfentanil injection crosses the placenta. Therefore, Alfentanil injection should only be used during labour after weighing the needs of the mother against the risk to the foetus. If Alfentanil injection is administered, assisted ventilation equipment must be immediately available for use if required for the mother and infant. An opioid antagonist for the child must always be available. The half-life of the opioid antagonist may be shorter than the half-life of alfentanil, therefore, repeated administration of the opioid antagonist may be necessary.

Although no teratogenic or acute embryotoxic effects have been observed in animal experiments, insufficient data are available to evaluate any harmful effects in man. Consequently, it is necessary to consider the possible risks and potential advantages before administering this medicine to pregnant patients.

Breastfeeding

Alfentanil injection may be excreted in human milk. Therefore, breastfeeding or use of expressed breast milk is not recommended during the 24 hours following the administration of Alfentanil injection.

4.7 Effects on ability to drive and use machines

Driving and the operation of machines can be resumed when sufficient time has elapsed following administration of Alfentanil injection. Individual reactions vary greatly. It is recommended that patients not drive or use machines for at least 24 hours after administration of Alfentanil injection.

4.8 Undesirable effects

Clinical Trial Data

The safety of Alfentanil injection was evaluated in 1157 subjects who participated in 18 clinical trials. Alfentanil injection was administered as an anaesthetic induction agent or as an analgesic/anaesthesia adjuvant to regional and general anaesthesia, in short, medium, and long surgical procedures. These subjects took at least one dose of Alfentanil injection and provided safety data. Adverse Drug

Reactions (ADRs) that were reported for ≥1% of Alfentanil injection-treated subjects in these trials are shown in Table 1.

Table 1. Adverse Drug Reactions Reported by ≥1% of Alfentanil injection-treated Subjects in 18 Clinical Trials of Alfentanil injection

System / Organ Class Adverse Reaction	Alfentanil injection (n=1157) %
Psychiatric Disorders	
Euphoric mood	1.8
Nervous System Disorders	
Movement disorder	7.9
Dizziness	2.4
Sedation	1.5
Dyskinesia	1.4
Eye Disorders	
Visual disturbance	1.1
Cardiac Disorders	
Bradycardia	5.4
Tachycardia	1.0
Vascular Disorders	
Hypotension	4.1
Hypertension	2.2
Blood pressure decreased	1.3
Blood pressure increased	1.0
Respiratory, Thoracic and Mediastinal Disorders	
Apnoea	8.6
Gastrointestinal Disorders	
Nausea	17.0
Vomiting	14.0
Musculoskeletal and Connective Tissue Disorders	
Muscle rigidity	3.1
General Disorders and Administration Site Conditions	
Fatigue	2.0
Chills	1.8
Injection site pain	1.6
Injury, Poisoning, and Procedural Complications	
Procedural pain	1.1

Additional ADRs that occurred in <1% of Alfentanil injection-treated subjects in the 18 clinical trials are listed below in Table 2.

Table 2. Adverse Drug Reactions Reported by <1% of Alfentanil injection-treated Subjects in 18 Clinical Trials of Alfentanil injection

System / Organ Class Adverse Reaction
Psychiatric Disorders
Agitation
Crying
Nervous System Disorders
Headache
Somnolence
Unresponsive to stimuli
Cardiac Disorders
Arrhythmia
Heart rate decreased
Vascular Disorders
Vein pain
Respiratory, Thoracic and Mediastinal Disorders
Bronchospasm
Hiccups
Hypercapnia
Laryngospasm
Epistaxis
Respiratory depression
Skin and Subcutaneous Tissue Disorders
Dermatitis allergic
Hyperhidrosis
Pruritus
General Disorders and Administration Site Conditions
Pain
Injury, Poisoning and Procedural Complications
Confusion postoperative
Agitation postoperative
Airway complication of anaesthesia
Anaesthetic complication neurological
Procedural complication
Endotracheal intubationcomplication

Post-marketing Data

Adverse drug reactions first identified during post-marketing experience with Alfentanil injection are included in Table 3. The frequencies are provided according to the following convention:

Very common	≥1/10
Common	≥1/100 and <1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000, <1/1,000
Very rare	<1/10,000, including isolated reports

In Table 3, ADRs are presented by frequency category based on spontaneous reporting rates.

Table 3. Adverse Drug Reactions Identified During Post-Marketing Experience with Alfentanil injection by Frequency Category Estimated from Spontaneous Reporting Rates

Immune System Disorders	
Very rare	Hypersensitivity (including anaphylactic reaction, anaphylactoid reaction, and urticaria)
Psychiatric Disorders	
Very rare	Disorientation
Nervous System Disorders	
Very rare	Loss of consciousness[a], Convulsion, Myoclonus
Eye Disorders	
Very rare	Miosis
Cardiac Disorders	
Very rare	Cardiac arrest
Respiratory, Thoracic and Mediastinal Disorders	
Very rare	Respiratory arrest, Respiratory depression[b], Cough
Skin and Subcutaneous Tissue Disorders	
Very rare	Erythema, Rash
General Disorders and Administration Site Conditions	
Very rare	Pyrexia

[a] Postoperative period.
[b] Including fatal outcome.

Although it is unlikely, alfentanil could cause opioid dependence, and has the potential for being abused. See also Section 4.4 Special warnings and precautions for use.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Signs and Symptoms

The manifestations of Alfentanil injection overdose are an extension of its pharmacological actions. Depending on the individual sensitivity, the clinical picture is determined primarily by the degree of respiratory depression, which varies from bradypnoea to apnoea.

Treatment

In the presence of hypoventilation or apnoea, oxygen should be administered, and respiration should be assisted or controlled as indicated. A specific opioid antagonist, such as naloxone, should be used as indicated to control respiratory depression. This does not preclude the use of more immediate countermeasures. The respiratory depression may last longer than the effect of the antagonist, therefore, additional doses of the latter may be required.

If depressed respiration is associated with muscular rigidity, an intravenous neuromuscular blocking agent may be required to facilitate assisted or controlled respiration.

The patient should be carefully observed, body warmth and adequate fluid intake should be maintained. If hypotension is severe or if it persists, the possibility of hypovolaemia should be considered, and if present, it should be controlled with appropriate parenteral fluid administration.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: opioid anaesthetics, ATC Code: N01AH02

Mechanism of action

Alfentanil is a potent, short acting, opioid analgesic chemically related to fentanyl.

The onset of action of alfentanil is more rapid than that of an equianalgesic dose of fentanyl and the maximal analgesic and respiratory depressant effect occurs within 1 to 2 minutes.

The duration of action of alfentanil is shorter than that of an equianalgesic dose of fentanyl and is dose- related. For analgesia lasting longer than 60 minutes, an infusion is preferable.

The depressant effect of alfentanil on respiratory rate and alveolar ventilation lasts for a shorter time than that of fentanyl. In most cases, the duration of analgesia exceeds that of the respiratory depression. The duration and degree of respiratory depression tend to be dose related.

At higher doses (>120 micrograms/kg), alfentanil can be used as an anaesthetic induction agent. The induction is smooth, pain-free and devoid of cardiovascular and hormonal stress responses to intubation.

The safety margin of alfentanil is comparatively better than that of other opioid analgesics. In rats, the ratio of LD50/ED50 for the lowest level of analgesia for alfentanil is 1080 compared with 4.6, 69.5 and 277 for pethidine, morphine and fentanyl, respectively.

Depending upon the dose and speed of administration, alfentanil can cause muscle rigidity, as well as euphoria, miosis and bradycardia, which is common with other opioid analgesics.

At doses up to 200 micrograms/kg, alfentanil failed to produce a significant increase in histamine levels or any clinical evidence of histamine release.

Recovery after alfentanil administration is rapid and smooth, with a low incidence of post-operative nausea and vomiting.

A specific opioid antagonist, such as naloxone immediately and completely reverses all actions of alfentanil.

5.2 Pharmacokinetic properties

Alfentanil is a synthetic opioid with μ-agonist pharmacologic effects, used only intravenously.

Distribution

The sequential distribution half-lives of alfentanil are 0.4 - 2.2 minutes and 8 - 32 minutes, Plasma

protein binding of alfentanil is about 92%. This and the low degree of ionisation (11% at pH = 7.4), contributes to a rapid but limited tissue distribution. Reported volumes of distribution are 1.27 - 4.81 L (volume of distribution of the central compartment) and 12.1 - 98.2 L (volume of distribution at steady state).

Metabolism

Alfentanil is metabolised mainly by the liver with only 1% of the active substance found unaltered in the urine. The metabolites are inactive and 70% to 80% of the metabolites are eliminated via the urine.

Elimination

Alfentanil is rapidly eliminated after intravenous administration. Terminal elimination half-lives of 83-223 min have been reported. The plasma clearance in young subjects averages 356 mL/min and decreases with age. Only 1% of unchanged alfentanil is found in urine. Once steady state has been reached after infusion, the elimination half-life remains unaltered.

Patient recovery (i.e. return to consciousness) generally occurs rapidly on discontinuation of alfentanil.

Special Populations

Paediatrics

Protein binding in newborns is 75% and increases in children to 85%. The plasma clearance in newborns is approximately 7.2 ± 3.2mL/kg/min and 4.7 ± 1.7 mL/kg/min in children between 4.5 to 7.75 years. The volume of distribution at steady state was 1230 ± 520 mL/kg in newborns and 163.5 ± 110 mL/kg in children. The half-life is 146 ± 57 minutes in newborns and 40.2 ± 8.9 minutes in children.

Hepatic Impairment

After administration of a single intravenous dose of 50 µg/kg, the terminal half-life in cirrhotic patients is significantly longer than in controls. The volume of distribution remains unchanged. The free fraction of alfentanil increases in cirrhotic patients to 18.5% compared with 11.5% in controls. This increase in free fraction together with a reduction in clearance from 3.06 mL/min/kg in controls to 1.60 mL/min/kg in cirrhotic patients will result in a more prolonged and pronounced effect (see Section 4.4 Special warnings and precautions for use).

Renal Impairment

The volume of distribution and clearance of the free fraction is similar in renal failure patients and healthy controls. The free fraction of alfentanil in patients with renal failure is increased to 12.4 to 19 % compared with 10.3 to 11% in controls. This may result in an increase in clinical effect of alfentanil (see Section 4.4 Special warnings and precautions for use).

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride

Water for injections

Sodium hydroxide

The solution does not contain any antioxidant or preservative.

6.2 Incompatibilities

Alfentanil injection must not be mixed with products other than those listed under Section 4.2 Dose and method of administration.

6.3 Shelf life

3 years

The prepared infusion should commence as soon as possible after its preparation and within 24 hours of preparation. See Section 4.2 DOSAGE AND METHOD OF ADMINISTRATION, For procedures of medium duration.

6.4 Special precautions for storage

Store below 25°C.

Any storage of the prepared solution should be at 2 - 8°C. See Section 4.2 DOSAGE AND METHOD OF ADMINISTRATION, For procedures of medium duration.

6.5 Nature and contents of container

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

Presentation	Pack Size (Ampoules)
1 mg/2 mL	1 x 2 mL, 5 x 2 mL, 10 x 2 mL
5 mg/10 mL	1 x 10 mL, 5 x 10 mL, 10 x 10 mL

Not all pack sizes may be distributed in New Zealand.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MEDICINE SCHEDULE

Controlled Drug (B3)

8 SPONSOR

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Marketed and distributed by Medsurge Healthcare.

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10 DATE OF REVISION OF THE TEXT

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SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
6.3	Updated shelf-life