1.3.1 Summary of Product Characteristics (SmPC)

1.3 Product Information

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1. NAME OF THE MEDICINAL PRODUCT:

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International Non-Proprietary Name:

ISOFLURANE USP 250 ml

ISOFLORIN

1.2 STRENGTH

250 ml/ Bottle

1.3 PHARMACEUTICAL FORM

Liquid For Inhalation

Description: A clear, colorless, volatile liquid having a slight odour

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 QUALITATIVE DECLARATION

Isoflurane USP

2.2 QUANTITATIVE DECLARATION

Each Botte Contains:

Isoflurane USP ..... 250 ml

3. PHARMACEUTICAL FORM

Liquid for Inhalation

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Isoflurane USP 250 ml is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Premedication should be selected according to the need of the individual patient, and at the discretion of the anesthetist. Surgical Anesthesia: Isoflurane should be delivered via a vaporizer specifically calibrated for use with Isoflurane so that the concentration delivered can be accurately controlled. MAC (minimum alveolar concentration) values for Isoflurane decrease with age and with the addition of nitrous oxide. The table below indicates average MAC values for different age groups.

Induction: Dosage should be individualised and titrated to the desired effect according to the patient's age and clinical status. A short acting barbiturate or other intravenous induction agent may be administered followed by inhalation of Isoflurane. Induction with Isoflurane may be achieved in oxygen or in combination with oxygen-nitrous oxide mixtures. In adults inspired concentrations of up to 5% Isoflurane usually produce surgical anaesthesia in less than 2 minutes. In children, inspired concentrations of up to 7% Isoflurane usually produce surgical anaesthesia in less than 2 minutes. Alternatively, for induction of anaesthesia in unpremedicated patients, inspired concentrations of up to 8% Isoflurane may be used. **Maintenance:** Surgical levels of anaesthesia may be sustained with concentrations of 0.5 - 3% Isoflurane with or without the concomitant use of nitrous oxide. Emergence: Emergence times are generally short following Isoflurane anaesthesia. Therefore, patients may require early post-operative pain relief.

Use in Special Population: Pregnancy: Isoflurane has a relaxant effect on the uterus, which can lead to increased uterine bleeding. Use during labour and delivery is limited to one small study in caesarean section. There are no adequate and well-controlled studies in pregnant women; therefore, Isoflurane should be used during pregnancy only if clearly needed. **Breastfeeding:** It is not known whether Isoflurane or its metabolites are excreted in human milk. Due to the absence of documented experience, women should be advised to skip breastfeeding for 48 hours after administration of Isoflurane and discard milk produced during this period.

Labour and Delivery: In a clinical trial, the safety of Isoflurane was demonstrated for mothers and infants when used for anaesthesia during Caesarean section. The safety of Isoflurane in labour and vaginal delivery has not been demonstrated.

4.3 CONTRAINDICATIONS

Isoflurane should not be used in patients with known or suspected sensitivity to Isoflurane or other halogenated anaesthetics (e.g. history of liver function disorder, fever or leucocytosis of unknown cause after anaesthesia with one of these agents). Isoflurane is also contraindicated in patients with known or suspected genetic susceptibility to malignant

hyperthermia. Isoflurane is contraindicated in patients in whom general anaesthesia is contraindicated.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Isoflurane may cause respiratory depression, which may be augmented by narcotic premedication or other agents causing respiratory depression. Respiration should be supervised and if necessary, assisted. Isoflurane should be administered only by persons trained in the administration of general anaesthesia. Facilities for maintenance of a patent airway, artificial ventilation, oxygen enrichment and circulatory resuscitation must be immediately available. The concentration of Isoflurane being delivered from a vaporizer must be known exactly. As volatile anaesthetics differ in their physical properties, only vaporisers specifically calibrated for Isoflurane must be used. The administration of general anaesthesia must be individualised based on the patient's response. Hypotension and respiratory depression increase as anaesthesia is deepened.

Malignant Hyperthermia : In susceptible individuals, potent inhalation anaesthetic agents may trigger a skeletal muscle hypermetabolic state leading to high oxygen demand and the clinical syndrome known as malignant hyperthermia. The clinical syndrome is signalled by hypercapnia, and may include muscle rigidity, tachycardia, tachypnoea, cyanosis, arrhythmias, and/or unstable blood pressure. Some of these nonspecific signs may also appear during light anaesthesia, acute hypoxia, hypercapnia and hypovolaemia. Treatment includes discontinuation of triggering agents (e.g. Isoflurane), administration of intravenous dantrolene sodium (consult prescribing information for intravenous dantrolene sodium for additional information on patient management), and application of supportive therapy. Such therapy includes vigorous efforts to restore body temperature to normal, respiratory and circulatory support as indicated, and management of electrolyte-fluid-acid-base abnormalities. Renal failure may appear later, and urine flow should be monitored and sustained if possible.

Perioperative Hyperkalemia : Use of inhaled anaesthetic agents has been associated with rare increases in serum potassium levels that have resulted in cardiac arrhythmias and death in paediatric patients during the postoperative period. Patients with latent as well as overt neuromuscular disease, particularly Duchenne muscular dystrophy, appear to be most vulnerable. Concomitant use of succinylcholine has been associated with most, but not all, of these cases. These patients also experienced significant elevations in serum creatine kinase levels and, in some cases, changes in urine consistent with myoglobinuria. Despite the similarity in presentation to malignant hyperthermia, none of these patients exhibited signs or symptoms of muscle rigidity or hypermetabolic state. Early and aggressive intervention to treat the hyperkalaemia and resistant arrhythmias is recommended, as is subsequent evaluation for latent neuromuscular disease. Isolated reports of QT prolongation, very rarely associated with torsade de pointes (in exceptional cases, fatal), have been received. Caution should be exercised when

administering Isoflurane to susceptible patients. Isolated cases of ventricular arrhythmia were reported in paediatric patients with Pompe's disease. Caution should be exercised in administering general anaesthesia, including Isoflurane, to patients with mitochondrial disorders.

Hepatic : Very rare cases of mild, moderate and severe post-operative hepatic dysfunction or hepatitis with or without jaundice have been reported. Clinical judgment should be exercised when Isoflurane is used in patients with underlying hepatic conditions or under treatment with drugs known to cause hepatic dysfunction. Patients with repeated exposures to halogenated hydrocarbons, including Isoflurane, within a relatively short interval may have an increased risk of hepatic injury.

General : During the maintenance of anaesthesia, increasing the concentration of Isoflurane produces dose-dependent decreases in blood pressure. Excessive decrease in blood pressure may be related to depth of anaesthesia and in such instances may be corrected by decreasing the inspired concentration of Isoflurane. Particular care must be taken when selecting the dosage for patients who are hypovolaemic, hypotensive, or otherwise hemodynamically compromised, e.g., due to concomitant medications. As with all anaesthetics, maintenance of haemodynamic stability is important to avoid myocardial ischaemia in patients with coronary artery disease. Caution should be observed when using Isoflurane during obstetric anaesthesia because the relaxant effect on the uterus could increase the risk of uterine bleeding. The recovery from general anaesthesia should be assessed carefully before patients are discharged from the recovery room. Rapid emergence from anaesthesia is generally seen with Isoflurane so early relief of postoperative pain may be required. Although recovery of consciousness following Isoflurane administration generally occurs within minutes, the impact on intellectual function for two or three days following anaesthesia has not been studied. As with other anaesthetics, small changes in moods may persist for several days following administration. Rapid emergence in children may be associated with agitation and lack of cooperation (in about 25% of cases).

Replacement of Desiccated CO2 Absorbents : Rare cases of extreme heat, smoke, and/or spontaneous fire in the anaesthesia machine have been reported during Isoflurane use in conjunction with the use of desiccated CO2 absorbent, specifically those containing potassium hydroxide (e.g Baralyme). An unusually delayed rise or unexpected decline of inspired Isoflurane concentration compared to the vaporiser setting may be associated with excessive heating of the CO2 absorbent canister. An exothermic reaction, enhanced Isoflurane degradation, and production of degradation products can occur when the CO2 absorbent becomes desiccated, such as after an extended period of dry gas flow through the CO2 absorbent canisters. Isoflurane degradants (methanol, formaldehyde, carbon monoxide, and Compounds A, B, C, and D) were observed in the respiratory circuit of an experimental anaesthesia machine using desiccated CO2 absorbents and maximum Isoflurane concentrations (8%) for extended periods of time (≥ 2 hours). Concentrations of formaldehyde observed at the anaesthesia respiratory circuit (using sodium hydroxide containing absorbents) were consistent with levels known to cause mild respiratory irritation. The clinical relevance of the degradants

88observed under this extreme experimental model is unknown. If a health care professional suspects that the CO2 absorbent has become desiccated, it must be replaced before subsequent use of volatile anaesthetics (such as Isoflurane). It must be taken into account that the colour indicator does not always change after desiccation has taken place. Therefore, the lack of significant colour change should not be taken as an assurance of adequate hydration. CO2 absorbents should be replaced routinely regardless of the state of the colour indicator.

Renal Impairment: Because of the small number of patients with renal insufficiency (baseline serum creatinine greater than 1.5mg/dL) studied, the safety of Isoflurane administration in this group has not been fully established. Therefore,

Isoflurane should be used with caution in patients with renal insufficiency. In some studies in rats, nephrotoxicity was seen in animals exposed to levels of Compound A

(pentafluoroisopropenyl fluoromethyl ether (PIFE)) in excess of those usually seen in routine clinical practice. The mechanism of this renal toxicity in rats is unknown and its relevance to ma88n has not been established.

Neurosurgery & Neuromuscular Impairment : In patients at risk from elevation of intracranial pressure, Isoflurane should be administered cautiously in conjunction with techniques to lower intra-cranial pressure (e.g. hyperventilation).

Seizures : Rare cases of seizures have been reported in association with Isoflurane use. Use of Isoflurane has been associated with seizures occurring in children and young adults as well as older adults with and without predisposing risk factors. Clinical judgment is necessary before Isoflurane is used in patients at risk of seizures. In children the depth of anaesthesia should be limited. EEG may permit the optimization of Isoflurane dose and help avoid the development of seizure activity in patients with a predisposition for seizures.

Paediatric population : The use of Isoflurane has been associated with seizures.
Many have occurred in children and young adults starting from 2 months of age, most of whom had no predisposing risk factors. Clinical judgment should be exercised when using Isoflurane in patients who may be at risk for seizures. Dystonic movements in children have been observed.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Beta-sympathomimetic agents like isoprenaline and alpha- and betasympathomimetic agents like adrenaline and noradrenaline should be used with caution during Isofluranenarcosis, due to a potential risk of ventricular arrhythmia. Non-selective MAOinhibitors: Risk of crisis during the operation. It is generally recommended that treatment should be stopped 2 weeks prior to surgery. Isoflurane may lead to marked hypotension in patients treated with calcium antagonists, in particular dihydropyridine derivates. Caution should be exercised when calcium antagonists are used concomitantly with inhalation anesthetics due to the risk of additive negative inotropic effect. Concomitant use of succinylcholine with inhaled anesthetic agents has been associated with rare increases in serum potassium levels that have resulted in cardiac

arrhythmias and death in pediatric patients during the post-operative period. Isoflurane has been shown to be safe and effective when administered concurrently with a wide variety of agents commonly encountered in surgical situations such as central nervous system agents, autonomic drugs, skeletal muscle relaxants, anti-infective agents including aminoglycosides, hormones and synthetic substitutes, blood derivatives and cardiovascular drugs, including epinephrine.

Epinephrine/Adrenaline : Isoflurane is similar to isoflurane in the sensitisation of the myocardium to the arrhythmogenic effect of exogenously administered adrenaline. Indirectacting Sympathomimetics : There is a risk of acute hypertensive episode with the concomitant use of Isoflurane and indirect-acting sympathomimetics products (amphetamines, ephedrine).

Beta blockers : Isoflurane may increase the negative inotropic, chronotropic and dromotropic effects of beta blockers (by blocking cardiovascular compensatory mechanisms). Verapamil : Impairment of atrioventricular conduction was observed when verapamil and Isoflurane were administered at the same time.

Inducers of CYP2E1 : Medicinal products and compounds that increase the activity of cytochrome P450 isoenzyme CYP2E1, such as isoniazid and alcohol, may increase the metabolism of Isoflurane and lead to significant increases in plasma fluoride concentrations. Concomitant use of Isoflurane and isoniazid can potentiate the hepatotoxic effects of isoniazid.

St John's Wort : Severe hypotension and delayed emergence from anaesthesia with halogenated inhalational anaesthetics have been reported in patients treated long-term with St John's Wort.

Barbiturates : Isoflurane administration is compatible with barbiturates as commonly used in surgical practice.

Benzodiazepines and Opioids : Benzodiazepines and opioids are expected to decrease the MAC of Isoflurane in the same manner as with other inhalational anaesthetics. Isoflurane administration is compatible with benzodiazepines and opioids as commonly used in surgical practice.

Opioids such as alfentanil and sufentail, when combined with Isoflurane, may lead to a synergistic fall in heart rate, blood pressure and respiratory rate.

Nitrous Oxide : As with other halogenated volatile anaesthetics, the MAC of Isoflurane is decreased when administered in combination with nitrous oxide. The MAC equivalent is reduced approximately 50% in adult and approximately 25% in paediatric patients. Neuromuscular Blocking Agents : As with other inhalational anaesthetic agents, Isoflurane affects both the intensity and duration of neuromuscular blockade by nondepolarising muscle relaxants. When used to supplement alfentanil-N2O anaesthesia, Isoflurane potentiates neuromuscular block induced with pancuronium, vecuronium or atracurium. The dosage adjustments for these muscle relaxants when administered with Isoflurane are similar to those

required with isoflurane. The effect of Isoflurane on succinylcholine and the duration of depolarising neuromuscular blockade has not been studied.

Dosage reduction of neuromuscular blocking agents during induction of anaesthesia may result in delayed onset of conditions suitable for endotracheal intubation or inadequate muscle relaxation because potentiation of neuromuscular blocking agents is observed a few minutes after the beginning of Isoflurane administration.

Among non-depolarising agents, vecuronium, pancuronium and atracurium interactions have been studied. In the absence of specific guidelines: (1) for endotracheal intubation, do not reduce the dose of non-depolarising muscle relaxants; and, (2) during maintenance of anaesthesia, the dose of non-depolarising muscle relaxants is likely to be reduced compared to that during N2O/opioid anaesthesia. Administration of supplemental doses of muscle relaxants should be guided by the response to nerve stimulation.

As with other agents, lesser concentrations of Isoflurane may be required following use of an intravenous anaesthetic e.g. propofol. Significant increases in plasma fluoride concentrations have been observed following the increased activity of CYP 2E1. Effects on ability to drive and use machines : As with other agents, patients should be advised that performance of activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, may be impaired for some time after general anaesthesia. Patients should not be allowed to drive for a suitable period after Isoflurane an aesthesia.

4.6 PREGNANCY AND LACTATION

Pregnancy : Isoflurane has a relaxant effect on the uterus, which can lead to increased uterine bleeding. Use during labour and delivery is limited to one small study in caesarean section. There are no adequate and well-controlled studies in pregnant women; therefore, Isoflurane should be used during pregnancy only if clearly needed.

Breastfeeding : It is not known whether Isoflurane or its metabolites are excreted in

human milk. Due to the absence of documented experience, women should be advised to skip breastfeeding for 48 hours after administration of Isoflurane and discard milk produced during this period.

Labour and Delivery : In a clinical trial, the safety of Isoflurane was demonstrated for mothers and infants when used for anaesthesia during Caesarean section. The safety of Isoflurane in labour and vaginal delivery has not been demonstrated.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

As with other agents, patients should be advised that performance of activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, may be impaired for some time after general anaesthesia.

Patients should not be allowed to drive for a suitable period after Isoflurane anaesthesia.

4.8 UNDESIRABLE EFFECTS

Summary of the safety profile

As with all potent inhaled anaesthetics, Isoflurane may cause dose-dependent cardiorespiratory depression. Most adverse reactions are mild to moderate in severity and are transient in duration. Nausea, vomiting and delirium are commonly observed in the postoperative period, at a similar incidence to those found with other inhalation anaesthetics.

These effects are common sequelae of surgery and general anaesthesia which may be due to the inhalational anaesthetic, other agents administered intra-operatively or postoperatively and to the patient's response to the surgical procedure.

The most commonly reported adverse reactions were as follows :
In adult patients: hypotension, nausea and vomiting.
In elderly patients: bradycardia, hypotension and nausea.
In paediatric patients: agitation, cough, vomiting and nausea.
Tabulated summary of adverse reactions : All adverse reactions at least possibly relating to Isofluranefrom clinical trials and post-marketing experience are as below. The following frequency categories are used: Very common (≥1/10); common

(≥1/100,<1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000),including isolated reports. Post-marketing adverse reactions are reported voluntarily from a population with an unknown rate of exposure. Therefore it is not

possible to estimate the true incidence of adverse events and the frequency is "unknown". The type, severity and frequency of adverse reactions in Isofluranepatients in clinical trials were comparable to adverse reactions in reference-drug patients.

Immune system disorders
Unknown: Anaphylactic reaction, Anaphylactoid reaction, Hypersensitivity
Blood and lymphatic system disorders
Uncommon: Leukopenia, Leukocytosis
Psychiatric disorders
Very Common: Agitation
Uncommon: Confusional state
Nervous system disorders
Common: Somnolence, Dizziness, Headache
Unknown: Convulsion, Dystonia
Cardiac disorders
Very Common: Bradycardia
Common: Tachycardia
Uncommon: Atrioventricular block complete, Atrial fibrillation, Arrythmia, Ventricular extrasystoles, Supraventricular extrasystoles, Extrasystoles
Unknown: Cardiac arrest, QT prolongation associated with Torsade
Vascular disorders
Very Common: Hypotension
Common: Hypertension
Respiratory, thoracic and mediastinal disorders Very
Common: Cough

Common: Respiratory disorder, Laryngospasm
Uncommon: Apnoea, Hypoxia, Asthma
Unknown: Bronchospasm, Dyspnoea, Wheezing, Pulmonary oedema
Gastrointestinal disorders
Very Common: Nausea, Vomiting
Common: Salivary hypersecretion
Renal and urinary disorders
Uncommon: Urinary retention, Glycosuria
Unknown: Renal failure acute
Hepato-biliary disorders
Unknown: Hepatitis, Hepatic failure, Hepatic necrosis
Skin and subcutaneous tissue disorders
Unknown: Dermatitis contact, Pruritus, Rash, Swelling face, Urticaria

Musculoskeletal and connective tissue disorders
Unknown: Muscle twitching
General disorders and administration site conditions
Common: Chills, Pyrexia, Hypothermia
Unknown: Chest discomfort, Hyperthermia malignant
Investigations
Common: Blood glucose abnormal, Liver function test abnormal, White blood cell count abnormal, Aspartate aminotransferase increased, Blood fluoride increased Uncommon: Alanine aminotransferase increased, Blood creatinine increased, Blood lactate dehydrogenase increased

Injury, poisoning and procedural complications
Common: Hypothermia
Description of selected adverse reactions
Transient increases in serum inorganic fluoride levels may occur during and after Isoflurane anaesthesia. Concentrations of inorganic fluoride generally peak within two hours of the end of Isoflurane anaesthesia and return within 48 hours to pre-operative levels. In clinical trials, elevated fluoride concentrations were not associated with impairment of renal function.

Rare reports of post-operative hepatitis exist. In addition, there have been rare postmarketing reports of hepatic failure and hepatic necrosis associated with the use of potent volatile anaesthetic agents, including Isoflurane. However, the actual incidence and relationship of Isoflurane to these events cannot be established with certainty. Rare reports of hypersensitivity (including contact dermatitis, rash, dyspnoea, wheezing, chest discomfort, swelling face, or anaphylactic reaction) have been received, particularly in association with long-term occupational exposure to inhaled anaesthetic agents, including Isoflurane. In susceptible individuals, potent inhalation anaesthetic agents may trigger a skeletal muscle hypermetabolic state leading to high oxygen demand and the clinical syndrome known as malignant hyperthermia.

Paediatric population : The use of Isoflurane has been associated with seizures. Many of

these have occurred in children and young adults starting from 2 months of age, most of whom had no predisposing risk factors. Clinical judgment should be exercised when using Isoflurane in patients who may be at risk for seizures.

4.9 OVERDOSE

In the event of overdosage, the following action should be taken: Stop drug administration, establish a clear airway and initiate assisted or controlled ventilation with pure oxygen and maintain adequate cardiovascular function.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC code: N01AB06 Cardiovascular

Effects

As with all other inhalation agents Isoflurane depresses cardiovascular function in a dose related fashion. In one volunteer study, increases in Isoflurane concentration resulted in decrease in mean arterial pressure, but there was no change in heart rate.

Isoflurane did not alter plasma noradrenaline concentrations in this study.

Nervous System Effects

No evidence of seizure was observed during the clinical development programme. In patients with normal intracranial pressure (ICP), Isoflurane had minimal effect on ICP and preserved CO2 responsiveness. The safety of Isoflurane has not been investigated in patients with a raised ICP. In patients at risk for elevations of ICP, Isoflurane should be administered cautiously in conjunction with ICP-reducing manoeuvres such as hyperventilation.

5.2 PHARMACOKINETIC PROPERTIES

The low solubility of Isoflurane in blood should result in alveolar concentrations which rapidly increase upon induction and rapidly decrease upon cessation of the inhaled agent. In humans <5% of the absorbed Isoflurane is metabolised. The rapid and extensive pulmonary elimination of Isoflurane minimises the amount of anaesthetic available for metabolism. Isoflurane is defluorinated via cytochrome p450(CYP)2E1 resulting in the production of hexafluoroisopropanol (HFIP) with release of inorganic fluoride and carbon dioxide (or a one carbon fragment). HFIP is then rapidly conjugated with glucuronic acid and excreted in the urine. The metabolism of Isoflurane may be increased

by known inducers of CYP2E1 (e.g. isoniazid and alcohol), but it is not inducible by barbiturates. Transient increases in serum inorganic fluoride levels may occur during and after Isoflurane an aesthesia. Generally concentrations of inorganic fluoride peak within 2 hours of the end of Isoflurane an aesthesia and return within 48 hours to pre-operative levels.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS None.

6.2 INCOMPATIBILITIES

None stated.

6.3 SHELF LIFE

36 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30ºC.

KEEP OUT OF REACH OF CHILDREN

6.5 NATURE AND CONTENTS OF CONTAINER

250 ml Amber color glass Bottle with Plastic black color cap with plastic U plug and with ring pull packed into the carton with insert.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Not Applicable

7. APPLICANT/MANUFACTURER

Manufactured for:

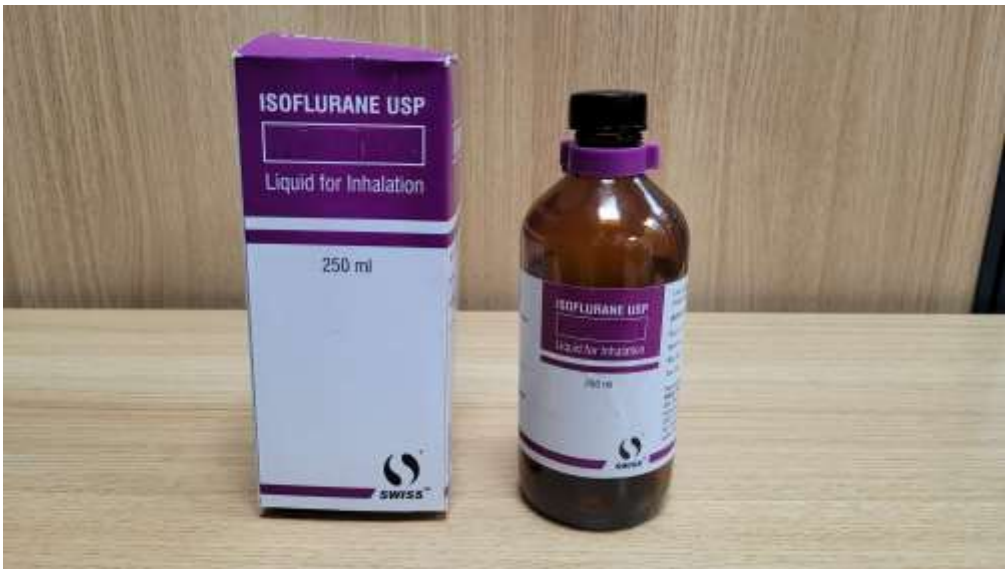
JAWA INTERNATIONAL LTD.

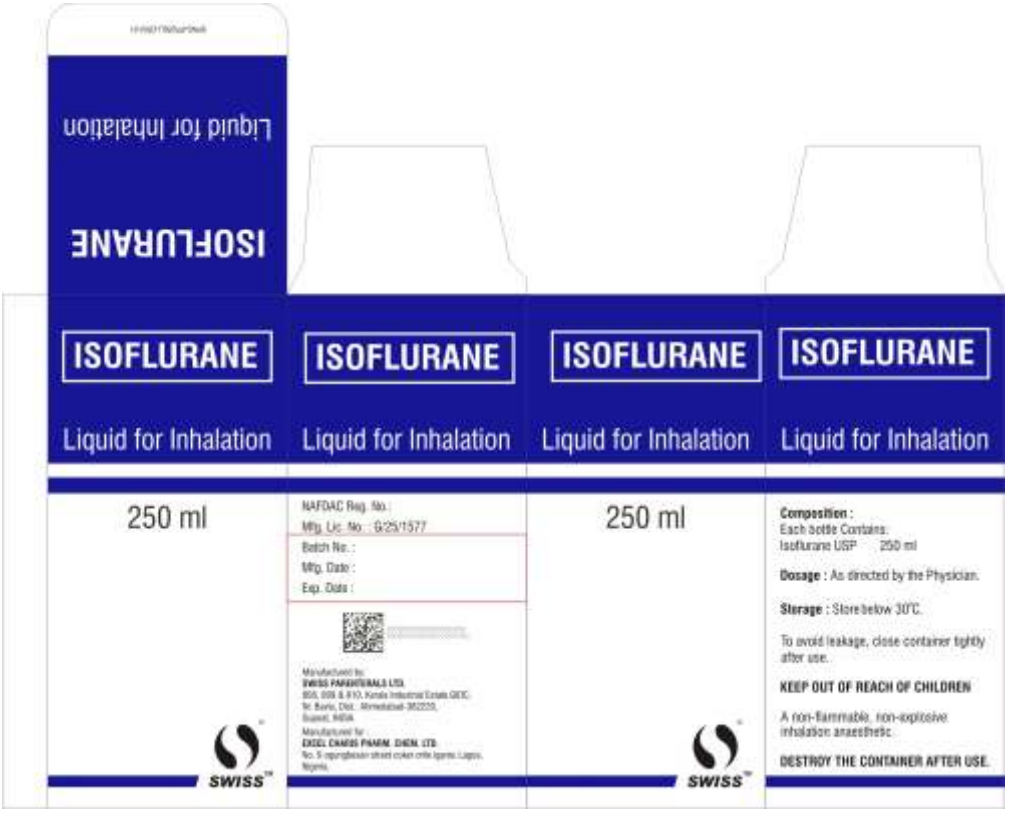
PLOT 6, ABIMBOLA WAY, ISOLO INDUSTRIAL ESTATE,
ISOLO, LAGOS, NIGERIA

Manufactured By:
SWISS PARENTERALS LIMITED

Manufacturing site : 808,809 & 810, Kerala Industrial Estate,
GIDC Nr. Bavla, Dist. Ahmedabad - 382 220

Gujarat, (INDIA)
Tel: +91-7968219120/111
Email : export@swiss.in


ISOFLURANE USP
Liquid for Inhalation
250 ml
SWISS


ISOFLURANE
Liquid for Inhalation
ISOFLURANE
Liquid for Inhalation
250 ml
SWISS
ISOFLURANE
Liquid for Inhalation
NAFDAC Reg. No.:
Mfg. Lic. No. : G/25/1577
Batch No. :
Mfg. Date :
Exp. Date :
ISOFLURANE
Liquid for Inhalation
250 ml
SWISS
ISOFLURANE
Liquid for Inhalation
Composition :
Each bottle Contains:
Isoflurane USP 250 ml
Dosage : As directed by the Physician.
Storage : Store below 30°C.
To avoid leakage, close container tightly after use.
KEEP OUT OF REACH OF CHILDREN
A non-flammable, non-explosive inhalation anaesthetic.
DESTROY THE CONTAINER AFTER USE.