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Halocarbon bottled Sevoflurane Inhalation Anesthesia, USP

Halocarbon is a pioneer in fluorinated anesthetics with nearly two decades of experience manufacturing Sevoflurane and is one of the world's foremost manufacturers of one of the product's key raw materials, hexafluoroisopropanol (HFIP).

We control the entire manufacturing process – through three synthesis steps – from active pharmaceutical ingredient (API) to bottled product. This makes Halocarbon a leading supplier of cost-effective bottled Sevoflurane to distributors and pharmaceutical companies worldwide.

- Manufactured and bottled in South Carolina, USA
- Direct shipping to the global marketplace
- Shipped in amber glass bottles for maximum stability
- 250mL USP Type III bottle (6 per case)
- 48-month shelf life
- Also available for veterinary use

For more information visit our website or contact a Halocarbon representative.

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Indication:

Sevoflurane is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery.

Sevoflurane should be administered only by persons trained in the administration of general anesthesia. Facilities for maintenance of a patent airway, artificial ventilation, oxygen enrichment, and circulatory resuscitation must be immediately available. Since level of anesthesia may be altered rapidly, only vaporizers producing predictable concentrations of sevoflurane should be used.

Important safety Information:

Sevoflurane is contraindicated in patients with known or suspected genetic susceptibility to malignant hyperthermia or known or suspected sensitivity to Sevoflurane or to other halogenated inhalational anesthetics.

In Susceptible individuals, volatile anesthetic agents, including sevoflurane, may trigger malignant hyperthermia, a skeletal muscle hypermetabolic state leading to high oxygen demand. Fatal outcomes of malignant hyperthermia have been reported. Successful treatment of malignant hyperthermia depends on early recognition of the clinical signs. If malignant hyperthermia is suspected, discontinue all triggering agents (i.e., volatile agents and succinylcholine), administer intravenous dantrolene sodium, and initiate supportive therapies.

Sevoflurane may cause respiratory depression, which may be augmented by opioid premedication or other agents causing respiratory depression. Monitor respiration and, if necessary, assist with ventilation.

During the maintenance of anesthesia, increasing the concentration of sevoflurane produces dose- dependent decreases in blood pressure. Due to Sevoflurane's insolubility in blood, these hemodynamic changes may occur more rapidly than with other volatile anesthetics. Excessive decreases in blood pressure or respiratory depression may be related to depth of anesthesia and may be corrected by decreasing the inspired concentration of sevoflurane.

The use of sevoflurane has been associated with seizures. The majority of these have occurred in children and young adults starting from 2 months of age, most of whom had no predisposing risk factors. Clinical judgement should be exercised when using sevoflurane in patients who may be at risk of seizures.

Use of 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 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 creatinine 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 hyperkalemia and resistant arrhythmias is recommended as is subsequent evaluation for latent neuromuscular disease.

Reports of QT prolongation, associated with torsade de pointes (in exceptional cases, fatal), have been received. Caution should be exercised when administering sevoflurane to susceptible patients (e.g.,patients with congenital Long QT Syndrome or patients taking drugs that can prolong the QT interval).

Studies conducted in young animals and children suggest repeated or prolonged use of general anesthetic or sedation drugs in children younger than 3 years may have negative effects on their developing brains. Discuss with parents and caregivers the benefits , risks, and timing and duration of surgery or procedures requiring anesthetic and sedation drugs.

Episodes of severe bradycardia and cardiac arrest, not related to underlying congenital heart disease have been reported during anesthesia induction with sevoflurane in pediatric patients with Down syndrome. In most cases, bradycardia improved with decreasing the concentration of sevoflurane, manipulating the airway, or administering an anticholinergic or epinephrine.

Risk of renal injury- Although data from controlled clinical studies at low flow rates are limited, findings taken from patient and animal studies suggest that there is a potential for renal injury which is presumed due to Compound A. Animal and human studies demonstrate that sevoflurane administered for more than 2 MAC hours and at fresh gas flow rates of < 2 L/min may be associated with proteinuria and glycosuria. To minimize exposure to Compound A, sevoflurane exposure should not exceed 2 MAC hours at flow rates of 1 to < 2 L/min. Fresh gas flow rates < 1 L/min are not recommended. Because clinical experience in administering sevoflurane to patients with renal insufficiency(creatinine > 1.5mg/dL) is limited, its safety in these patients has not been established.

Performance of activities requiring mental alertness, such as driving or operating machinery, may be impaired after sevoflurane anesthesia.

Cases of mild, moderate and severe post-operative hepatic dysfunction or hepatitis with or without jaundice have been reported. Histological evidence was not provided for any of the reported hepatitis cases. In most of these cases, patients had underlying hepatic conditions or were under treatment with drugs known to cause hepatic conditions or were under treatment with drugs known to cause hepatic dysfunction. Most of the reported events were transient and resolved spontaneously. Clinical judgement should be exercised when sevoflurane is used in patients with underlying hepatic conditions or under treatment with drugs known to cause hepatic dysfunction. It has been reported that previous exposure to halogenated hydrocarbon anesthetics may increase the potential for hepatic injury.

Drug Interactions: Epinephrine administered with Sevoflurane may increase risk of ventricular arrhythmias. Monitor electrocardiogram and blood pressure and ensure availability of emergency medications. Sevoflurane may lead to marked hypotension in patients treated with calcium antagonists. Monitor blood pressure availability of emergency medications in these patients. Concomitant use of MAO inhibitors and inhalational anesthetics may increase risk of hemodynamic instability. Benzodiazepines and opioids would be expected to decrease the MAO of sevoflurane. The anesthetic requirement for sevoflurane is decreased when administered in combination with nitrous oxide. Sevoflurane increases both the intensity and duration of neuromuscular blockade induced by nondepolarizing muscle relaxants.

Adverse events reported by ≥ 5% of the surgical patients receiving Sevoflurane during clinical trials during induction included: bradycardia, tachycardia, agitation laryngospasm, airway obstruction, breath-holding, and increased cough; during maintenance and emergence: shivering, hypotension, bradycardia, somnolence, agitation, nausea, vomiting, and increased cough were reported.

Adverse events during the induction period (from onset of Anesthesia by Mask Induction to Surgical Incision) in adults at an Incidence >1% include Bradycardia, Hypotension, Tachycardia, Agitation, Laryngospasm, Airway Obstruction, Breathholding, Cough increased ;In pediatric patients during induction at incidence >1% include Tachycardia, Hypotension, Agitation, Breatholding, Cough increased, Laryngospasm, Apnea and Increased salivation.

Adverse events during maintenance and emergence period, incidence >1 % include fever, shivering, hypothermia, Movement, Headache ,hypotension, hypertension, Bradycardia, Tachycardia,somnolence, agitation, Dizziness, increased salivation, Nausea, vomting, nausea, vomiting, cough increased, breatholding, laryngospasm

Sevoflurane may present an increased risk in patients with known sensitivity to volatile halogenated anesthetic agents. KOH containing CO2 absorbents are not recommended for use with sevoflurane.