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 patient 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.

Sevoflurane can cause malignant hyperthermia. Postmarketing reports of malignant hyperthermia, some of which have been fatal, have occurred. Sevoflurane should not be used in patients with known sensitivity to Sevoflurane or to other halogenated agents, or in patients with known or suspected susceptibility to malignant hyperthermia.

Findings taken from patient and animal studies suggest that there is a potential for renal injury when Sevoflurane is used at low flow rates, which is presumed due to Compound A. The level of Compound A exposure at which clinical nephrotoxicity might be expected to occur has not been established. To minimize exposure to Compound A, Sevoflurane exposure should not exceed 2 MAC-hours at flow rates of $< 2$ L/min. Fresh gas flows $< 1$ L/min are not recommended.

Because clinical experience in administering Sevoflurane to patients with renal insufficiency (creatinine $> 1.5$ mg/dL) is limited, its safety in these patients has not been established.

Sevoflurane may be associated with glycosuria and proteinuria when used for long procedures at low flow rates.

KOH containing CO$_2$ absorbents are not recommended for use with Sevoflurane. An exothermic reaction occurs when Sevoflurane is exposed to CO$_2$ absorbents. This reaction is increased when the absorbent becomes desiccated. Rare cases of extreme heat, smoke, and/or spontaneous fire have been reported during Sevoflurane use in conjunction with the use of desiccated CO$_2$ absorbent, specifically those containing potassium hydrosulfide (e.g., Baralyme).

Reports of QT prolongation, associated with torseade 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).

Rane increases in serum potassium resulting in cardiac arrhythmias and death have been noted in pediatric patients during the postoperative period following the use of inhaled anesthetic agents. Contributing risk factors appear to be latent or overt neuromuscular disease, particularly Duchenne muscular dystrophy. Concomitant use of succinylcholine has been associated with this, but not all, of these cases. Early, aggressive intervention to treat both hyperkalemia and resistant arrhythmias, and subsequent evaluation for latent neuromuscular disease is recommended.

During the maintenance of anesthesia, increasing the concentration of Sevoflurane produces dose-dependent decreases in blood pressure. Due to Sevoflurane’s insulobility in blood, 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.

Sevoflurane is a volatile anesthetic that may be associated with glycosuria and proteinuria when used for long procedures at low flow rates. The safety of low flow sevoflurane on renal function was evaluated in patients with normal preoperative renal function. One study compared sevoflurane (N = 98) to an active control (N = 90) administered for $> 2$ hours at fresh gas flow rate of $< 1$ Liter/minute. Per study defined criteria (Hou et al.) one patient in the sevoflurane group developed elevations of creatinine, in addition to glycosuria and proteinuria. This patient received sevoflurane at fresh gas flow rates of $< 800$ mL/minute. Using these same criteria, there were no patients in the active control group who developed treatment emergent elevations in serum creatinine.

Sevoflurane may present an increased risk in patients with known sensitivity to volatile halogenated anesthetic agents. KOH containing CO$_2$ absorbents are not recommended for use with sevoflurane.

Sevoflurane should not be used in patients with known sensitivity to sevoflurane or to other halogenated agents nor in patients with known or suspected susceptibility to malignant hyperthermia.

Sevoflurane may be associated with glycosuria and proteinuria when used for long procedures at low flow rates.

KOH containing CO$_2$ absorbents are not recommended for use with Sevoflurane. An exothermic reaction occurs when Sevoflurane is exposed to CO$_2$ absorbents. This reaction is increased when the absorbent becomes desiccated. Rare cases of extreme heat, smoke, and/or spontaneous fire have been reported during Sevoflurane use in conjunction with the use of desiccated CO$_2$ absorbent, specifically those containing potassium hydrosulfide (e.g., Baralyme).

Reports of QT prolongation, associated with torseade 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).

Sevoflurane may cause malignant hyperthermia. It should not be used in patients with known sensitivity to sevoflurane or to other halogenated agents nor in patients with known or suspected susceptibility to malignant hyperthermia.

Warnings:

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 when Sevoflurane is used at low flow rates, which is presumed due to Compound A. The level of Compound A exposure at which clinical nephrotoxicity might be expected to occur has not been established. To minimize exposure to Compound A, Sevoflurane exposure should not exceed 2 MAC-hours at flow rates of $< 2$ L/min. Fresh gas flows $< 1$ L/min are not recommended.

Because clinical experience in administering Sevoflurane to patients with renal insufficiency (creatinine $> 1.5$ mg/dL) is limited, its safety in these patients has not been established.

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Reports of QT prolongation, associated with torseade 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).

Sevoflurane may cause malignant hyperthermia. It should not be used in patients with known sensitivity to sevoflurane or to other halogenated agents nor in patients with known or suspected susceptibility to malignant hyperthermia.

Warnings:

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. While a level of Compound A exposure at which clinical nephrotoxicity might be expected to occur has not been established. To minimize exposure to Compound A, sevoflurane exposure should not exceed 2 MAC·hours at flow rates of $< 2$ L/min. Fresh gas flows $< 1$ L/min are not recommended.