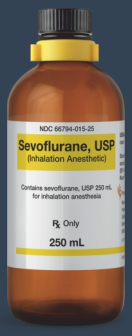
Inhalation Anesthesia

Piramal Critical Care



Sevoflurane, USP

Inhalation Anesthetic

- Manufactured in USA[1]
- 37% market share in USA[2]

1. Information in Piramal Critical Care files 2. IQVIA data MAT September 2021

Piramal's Sevoflurane, USP is available through the wholesaler or distributor of your choice

250 mL Order #'s	
NDC #	**66794-015-25**
AmerisourceBergen	10183807
Besse Medical	38263
Cardinal	4985206
CuraScript	83216
Henry Schein	116-9356
McKesson	1359868
McKesson Med/Surg	779244
Morris & Dickson	038760

Indication and important Safety Information you should know about Sevoflurane

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 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 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 1 to <2L/min. Fresh gas flow rates<1L/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 hydroxide (e. g., Baralyme).
- Reports of QT prolongation, associated with torsade de points (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).
- Rare increase 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 most, 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 decrease in blood pressure. Due to Sevoflurane's insolubility in blood, hemodynamic changes may occur more rapidly than with other volatile anesthetics. Excessive decrease in blood pressure or respiratory depression may be related to depth of anesthesia and may be corrected by decreasing the inspired concentration of Sevoflurane.
- Seizures have been reported in association with Sevoflurane use, the majority of which have occurred in children and young adults, most of whom had no predisposing risk factors. Clinical judgment should be exercised when using Sevoflurane in patients who may be at risk for seizures.
- Drug interactions: Benzodiazepines and opioids would be expected to decrease the MAC 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.
- Very rare cases of mild, moderate, and severe postoperative hepatic dysfunction or hepatitis with or without jaundice have been reported from postmarketing experiences. In addition, rare postmarketing reports of hepatic failure and hepatic necrosis have been associated with the use of Sevoflurane. Clinical judgment should be used in patients with underlying hepatic conditions or who are 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.
- 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.

For more information, please contact Piramal Customer Service at +1-800-414-1901 during business hours (8 a.m. EST to 5 p.m. EST) or e-mail at pcc.customerservice@piramal.com

- Full prescribing information of Sevoflurane, USP can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3dbab949-6ab7-4040-9c81-314e5bb61d41.
- Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.
- You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

"Saving and Improving Patients' Lives."

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