



Using ULTANE® (sevoflurane) in Mask Induction

Indication¹

ULTANE® (sevoflurane) is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery. ULTANE 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 ULTANE should be used.

 **ULTANE**
sevoflurane

abbvie

Mask Induction

What Is Mask Induction?

Mask induction typically utilizes an inhaled anesthetic agent, which allows a patient to quickly fall asleep and rapidly pass through the excitatory phase of anesthesia. The use of premedications is left to the discretion of the anesthesiologist who must take into account the patient's condition, the surgical procedure, and whether or not intubation will be established.

When Is Mask Induction an Appropriate Option?

- Pediatric surgery
- Short outpatient procedures
- Procedures involving peripheral sites, in which a neuromuscular blocker is not necessary and controlling ventilation is not required
- Procedures where an IV line is not required, is difficult to establish, or is not available
- Lack of other IV anesthetic induction agents



Mask Induction Techniques

The following information offers insights into the use of ULTANE in mask induction in adults. It is intended to complement (not substitute for) the clinical experience and judgment of the clinician.

Vital Capacity Single-Breath Induction*

- Patient training and compliance is required
 - The patient must be able to:
 - Exhale fully
 - Inhale fully
 - Hold breath as long as possible
 - This is practiced prior to applying face mask
- Patient may be preoxygenated with 100% O₂ for several minutes
- The anesthesia circuit is primed with ULTANE in nitrous oxide and oxygen
- Patient is instructed to exhale
- Oxygen mask is applied and the patient is instructed to breathe in deeply and hold for as long as possible (i.e., 30–60 seconds)[†]
- Tidal breathing until consciousness is lost
- When the appropriate anesthetic depth is reached, an oral airway can be placed

Vital Capacity Triple-Breath Induction*

The triple-breath induction technique is a variation of the single-breath method. In this technique, the patient is instructed to take 3 deep breaths over a period of 30–40 seconds.

*The use of anesthetic overpressure in these techniques accelerates the wash-in of ULTANE. Vigilance must be maintained to prevent anesthetic overdose when this practice is utilized, especially if controlled ventilation is initiated.

[†]If patient exhaled before losing consciousness, patients are instructed to take additional breaths until they are asleep.



Gradual Induction (Tidal Volume Technique)

- Slower than Vital Capacity Induction
- If patient is unpremedicated, mask acceptance may be enhanced with an initial, brief administration of nitrous oxide at an inhaled concentration of 50% to 70%
- Patient breathes oxygen with gradual increases of ULTANE
- The inspired concentration of ULTANE can be increased every 2–3 breaths until clinical signs of adequate anesthetic depth are observed (which usually occurs within 60–90 seconds)

Safety Considerations¹

- Reports of QT prolongation, associated with torsade de pointes (in exceptional cases, fatal), have been received. Caution should be exercised when administering ULTANE to susceptible patients (e.g. patients with congenital Long QT Syndrome or patients taking drugs that can prolong the QT interval).
- Due to ULTANE's insolubility 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 ULTANE.
- Drug interactions: Benzodiazepines and opioids would be expected to decrease the MAC of ULTANE. The anesthetic requirement for ULTANE is decreased when administered in combination with nitrous oxide. ULTANE increases both the intensity and duration of neuromuscular blockade induced by nondepolarizing muscle relaxants.
- Compound A exposure in patients has been shown to rise with increased ULTANE concentrations and duration of anesthesia. Nephrotoxicity produced by Compound A is dependent on dose and duration of exposure.

[Click here](#) for Important Safety Information.

[Click here](#) for full Prescribing Information.

ULTANE (sevoflurane) for Mask Induction

ULTANE for Mask Induction¹

- ULTANE is the only fast acting inhalational anesthetic suitable for mask induction in both adults and pediatric patients ≥ 1 year
- ULTANE has a nonpungent odor and does not cause respiratory irritability
- The low blood:gas solubility of ULTANE facilitates rapid induction and elimination
- 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 ULTANE

Safety Considerations¹

- ULTANE may be associated with glycosuria and proteinuria when used for long procedures at low flow rates.
- Rare 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 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.
- Seizures have been reported in association with ULTANE 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 ULTANE in patients who may be at risk for seizures.



Characteristics of ULTANE (sevoflurane)

ULTANE has a nonpungent odor and does not cause respiratory irritability. ULTANE is suitable for mask induction in adults and pediatric patients ≥ 1 year.

ULTANE Pharmacodynamics

Induction (Mean \pm SEM)

3.1 min \pm 0.18^a (n=93)

^aPropofol induction of one ULTANE group = mean of 178.8 mg \pm 72.5 SD (n=165).



Adverse Events During the Induction Period

- ULTANE Mask Induction in **Adults**
 - In 196 patients, mask induction was smooth and rapid, with complications occurring with the following frequencies: cough, 6%; breathholding, 6%; agitation, 6%; laryngospasm, 5%.
- ULTANE Mask Induction in **Pediatrics**
 - In controlled pediatric studies in which mask induction was performed, the incidence of induction events was: agitation, 14%; cough, 6%; breathholding, 5%; secretions, 3%; laryngospasm, 2%; bronchospasm, <1%.

Safety Considerations¹

- Sevoflurane can cause malignant hyperthermia. Postmarketing reports of malignant hyperthermia, some of which have been fatal, have occurred. ULTANE 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.
- Because clinical experience in administering ULTANE to patients with renal insufficiency (creatinine >1.5 mg/dL) is limited, its safety in these patients has not been established.
- Studies conducted in young animals and children suggest repeated or prolonged use of general anesthetic or sedation drugs in the third trimester of gestation through the first three years of age may result in adverse cognitive or behavioral effects on their developing brains. The studies in children have substantial limitations, and it is not clear if the observed effects are due to the anesthetic/sedation drug administration or other factors, such as the surgery or underlying illness. Anesthetic and sedation drugs are a necessary part of the care of children when needed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

IMPORTANT SAFETY INFORMATION¹

- ULTANE can cause malignant hyperthermia. Postmarketing reports of malignant hyperthermia, some of which have been fatal, have occurred. ULTANE 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 ULTANE 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, ULTANE 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 ULTANE to patients with renal insufficiency (creatinine >1.5 mg/dL) is limited, its safety in these patients has not been established.
- ULTANE may be associated with glycosuria and proteinuria when used for long procedures at low flow rates.
- KOH containing CO₂ absorbents are not recommended for use with ULTANE. An exothermic reaction occurs when ULTANE is exposed to CO₂ absorbents. This reaction is increased when the absorbent becomes desiccated. Rare cases of extreme heat, smoke, and/or spontaneous fire have been reported during ULTANE use in conjunction with the use of desiccated CO₂ absorbent, specifically those containing potassium hydroxide (e.g., Baralyme).
- Reports of QT prolongation, associated with torsade de pointes (in exceptional cases, fatal), have been received. Caution should be exercised when administering ULTANE to susceptible patients (e.g. patients with congenital Long QT Syndrome or patients taking drugs that can prolong the QT interval).
- Rare 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 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.
- Studies conducted in young animals and children suggest repeated or prolonged use of general anesthetic or sedation drugs in the third trimester of gestation through the first three years of age may result in adverse cognitive or behavioral effects on their developing brains. The studies in children have substantial limitations, and it is not clear if the observed effects are due to the anesthetic/sedation drug administration or other factors, such as the surgery or underlying illness. Anesthetic and sedation drugs are a necessary part of the care of children when needed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.
- Due to ULTANE's insolubility 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 ULTANE.
- Seizures have been reported in association with ULTANE 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 ULTANE in patients who may be at risk for seizures.
- Drug interactions: Benzodiazepines and opioids would be expected to decrease the MAC of ULTANE. The anesthetic requirement for ULTANE is decreased when administered in combination with nitrous oxide. ULTANE 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 ULTANE. 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 ULTANE during clinical trials during induction included: bradycardia, tachycardia, agitation, laryngospasm, airway obstruction, breathholding, and increased cough; during maintenance and emergence: shivering, hypotension, bradycardia, somnolence, agitation, nausea, vomiting, and increased cough were reported.

Reference: 1. ULTANE [package insert]. North Chicago, IL: AbbVie Inc.

[Click here](#) for full Prescribing Information.

The logo for ULTANE sevoflurane features a yellow square with a white checkmark on the left. To its right, the word "ULTANE" is written in a bold, blue, sans-serif font. Below "ULTANE", the word "sevoflurane" is written in a smaller, blue, lowercase, sans-serif font.