

Elderly

MAC decreases with increasing age. The average concentration of sevoflurane to achieve MAC in an 80 year old is approximately %50 of that required in a 20 year old. In adults, the MAC of Sevoflurane decreases by approximately %0.2 per decade of age.

In elderly patients, cardiovascular and renal function are frequently compromised. Sevoflurane does not affect the kidney's ability to concentrate urine and does not produce any other evidence of renal dysfunction.

Pregnancy

Sevoflurane has been used in clinical studies, as part of general anesthesia for elective cesarean section. There were no untoward effects in mother or neonate. Sevoflurane can cause uterine smooth muscle relaxation and may contribute to uterine atony and has the additional advantage of a less pronounced adverse effect on the cardiovascular system, particularly the heart rate.

Nursing Mothers

To minimize infant exposure to sevoflurane or its metabolites, a nursing mother may temporarily pump, and discard breast milk produced during the first 24 hours after administration of sevoflurane. Exercise caution when administering sevoflurane to a nursing mother.

Drug Interactions

In clinical studies, no significant adverse reactions occurred with other drugs commonly used in the perioperative period, including central nervous system depressants, autonomic drugs, skeletal muscle relaxants, anti-infective agents, hormones and synthetic substitutes, blood derivatives, and cardiovascular drugs.

Occupational Caution

There is no specific work exposure limit established for sevoflurane. However, the National Institute for Occupational Safety and Health has recommended an 8 hour time-weighted average limit of 2 ppm for halogenated anesthetic agents in general (0.5 ppm when coupled with exposure to N₂O).

Sevoflurane
250 ml

Inhalation anaesthetic

The right choice for anesthesia

- Ease of administration
- Low solubility
- Hemodynamic stability
- Rapid recovery
- Favorable Safety Profile



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SEVOFLURANE

Volatile liquid for inhalation

Product Name: Sevoflurane

Pharmaceutical Company: Abbvie Inc.

Distributed By: KMT (Khosro Medisa Teb)

Therapeutic Class: Inhalational Anesthetic

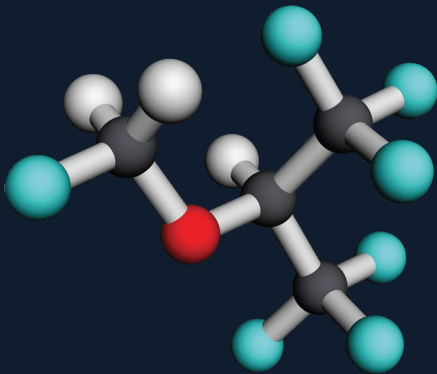
Indications: General anesthesia for induction and maintenance

Dosage Form: Inhalation liquid, 250 ml

Container Type: Supplied in polyethylene naphthalate (PEN) bottles

Administration Route: Inhalational (By vaporization)

Storage Conditions: Store at controlled room temperature, between 15°C - 30°C



DESCRIPTION

Sevoflurane (C₄H₇F₇O), volatile liquid for inhalation, a non-flammable, a non-pungent and non-explosive liquid, administered by vaporization, a halogenated general inhalation anesthetic drug.

CLINICAL PHARMACOLOGY

Sevoflurane is an inhalational anesthetic agent for use in induction and maintenance of general anesthesia. Minimum alveolar concentration (MAC) of sevoflurane in oxygen for a 40-year-old adult is 2.05 %. The MAC of

MAC VALUES FOR SEVOFLURANE

Age of Patients (years)	Sevoflutane in Oxygen (%)	Sevoflutane in 65% N ₂ O/35% O ₂ (%)
<3	2.6-3.3	2
5>-3	2.5	Not available
12-5	2.4	Not available
25	2.5	1.4
35	2.2	1.2
40	2.05	1.1
50	1.8	0.98
60	1.6	0.87
80	1.4	0.7

INDICATION & CONTRAINDICATION

Sevoflurane is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery. Since level of anesthesia may be altered rapidly, only vaporizers producing predictable concentrations of Sevoflurane should be used. Induction Sevoflurane has a non pungent odor and does not cause respiratory irritability. Maintenance surgical levels of anesthesia can usually be achieved with concentrations of 0.5 - 3% sevoflurane with or without the concomitant use of nitrous oxide.

Sevoflurane is contraindicated in the following cases:

- In patients with known sensitivity to sevoflurane or to other halogenated agents
- In patients with known or suspected genetic susceptibility to malignant hyperthermia, or in patients with a known or suspected history of malignant hyperthermia

BENEFICIAL EFFECTS OF SEVOFLURANE

Benefit	Description
High Steerability	<ul style="list-style-type: none">• Smooth, rapid loss of consciousness• Easy adjustment of depth of anaesthesia during maintenance• Rapid emergence
Positive CNS Effects	<ul style="list-style-type: none">• Does not impair autoregulation of cerebral blood flow• Causes only moderate vasodilation• Decreases cerebral metabolism
Maintains Cardiovascular Stability	<ul style="list-style-type: none">• Maintains heart rate• Does not significantly sensitise the myocardium to epinephrine• Maintains cardiac output and stroke volume• Not associated with "coronary steal"
Maintains Blood Flow	<ul style="list-style-type: none">• Maintains blood flow to vital organs (liver and kidney)
Respiratory Effects	<ul style="list-style-type: none">• Minimal airway irritation due to pleasant odour• Little airway secretion• Low incidence of cough and laryngospasm

EFFICACY IN SPECIAL POPULATION

Pediatric

Induction and maintenance of general anesthesia with sevoflurane have been established in controlled clinical studies in pediatric patients aged 1 to 18 years. Sevoflurane has a nonpungent odor and is suitable for mask induction in pediatric patients. The concentration of sevoflurane required for maintenance of general anesthesia is age dependent.

Significant complications following Sevoflurane anesthesia in children are rare. Unlike other inhalation gases, Sevoflurane poses no risk of halothane hepatitis, a serious form of hepatotoxicity, has less arrhythmogenic potential when administered alone or with epinephrine, and causes less cardiovascular depression. These benefits make Sevoflurane suitable for use in both induction and maintenance of anesthesia in children.

Mask Induction

Sevoflurane has a nonpungent odor and does not cause respiratory irritability. Sevoflurane is suitable for mask induction in adults.

Adult Anesthesia

The efficacy of sevoflurane in comparison to isoflurane, enflurane, and propofol was investigated in 3 outpatient and 25 inpatient studies involving 3591 adult patients. Sevoflurane was found to be comparable to isoflurane, enflurane, and propofol for the maintenance of anesthesia in adult patients. Patients administered sevoflurane showed shorter times (statistically significant) to some recovery events (extubation, response to command, and orientation) than patients who received isoflurane or propofol.