



4 Fierberg St. P.O.Box 2820 Holon 5812801 Israel
Tel: +972-(0)72-2555533 +972-(0)3-5057906
Fax: +972-(0)72-2555534 +972-(0)3-5059865
eMail: info@pharmamedis.com

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

SOJOURN SEVOFLURANE USP

חברת פארמה מדיס מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

התווית התכשיר:

Induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery

מרכיב פעיל: SEVOFLURANE 100%
צורת המתן של התכשיר: INHALATION

להלן העדכונים העיקריים בעלון לצרכן (במתכונת עלון לרופא):

WARNINGS

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).

Malignant hyperthermia

In clinical trials, one case of malignant hyperthermia was reported. In addition, there have been post marketing reports of malignant hyperthermia. Some of these cases have been fatal

Pediatric Neurotoxicity

Published animal studies demonstrate that the administration of anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of these findings is not clear. However, based on the available data, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but may extend out to approximately three years of age in humans (see **PRECAUTIONS - Pregnancy, PRECAUTIONS - Pediatric Use**).

Some published studies in children suggest that similar deficits may occur after repeated or prolonged exposures to anesthetic agents early in life and may result in adverse cognitive or behavioral effects. These studies 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 needing surgery, other procedures, or tests that cannot be delayed, 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.

PRECAUTIONS

Information for Patients

Effect of anesthetic and sedation drugs on early brain development

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 (see **WARNINGS - Pediatric Neurotoxicity**).



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Hepatic Function

It has been reported that previous exposure to halogenated hydrocarbon anesthetics may increase the potential for hepatic injury.

Pediatric Use

Published juvenile animal studies demonstrate that the administration of anesthetic and sedation drugs, such as **SOJOURN SEVOFLURANE USP**, that either block NMDA receptors or potentiate the activity of GABA during the period of rapid brain growth or synaptogenesis, results in widespread neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis. Based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but may extend out to approximately 3 years of age in humans.

In primates, exposure to 3 hours of ketamine that produced a light surgical plane of anesthesia did not increase neuronal cell loss; however, treatment regimens of 5 hours or longer of isoflurane increased neuronal cell loss. Data from isoflurane-treated rodents and ketamine-treated primates suggest that the neuronal and oligodendrocyte cell losses are associated with prolonged cognitive deficits in learning and memory. The clinical significance of these nonclinical findings is not known, and healthcare providers should balance the benefits of appropriate anesthesia in pregnant women, neonates, and young children who require procedures with the potential risks suggested by the nonclinical data (see **WARNINGS - Pediatric Neurotoxicity, PRECAUTIONS - Pregnancy**).

ADVERSE REACTIONS

Cardiac

Cardiac arrest

Reports of hypersensitivity (including contact dermatitis, rash, dyspnea, wheezing, chest discomfort, swelling face, or anaphylactic reaction) have been received, particularly in association with long-term occupational exposure to inhaled anesthetic agents, including sevoflurane (see **OCCUPATIONAL CAUTION**).

השינויים המודגשים ברקע צהוב מהווים החמרה. בעלון בוצעו שינויים נוספים אשר מהווים תוספת מידע.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: <https://data.health.gov.il/drugs/index.html#!/byDrug>
ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת פארמה-מדיס, פייירברג 4 חולון.

בברכה,

מירי חזן
רוקחת ממונה