רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת AbbVie Biopharmaceuticals Ltd. מודיעה כי העלון לרופא של התכשיר Sevorane עודכן.

בהודעה זו מצוינים סעיפים בהם נעשה שינוי אשר מהווה החמרה או שינוי מהותי.

עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (שינוי שהינו הוספה מסומן בקו תחתון, מחיקה מסומנת בקו אמצעי).

Sevorane

סבורן

Solution for inhalation

Sevoflurane 100%

ההתוויה המאושרת לתכשיר:

Sevoflurane is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery.

העלון לרופא עודכן בסעיפים:

INDICATIONS AND USAGE

מהות השינוי:

Sevoflurane 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 sevoflurane should be used.~~

The concentration of sevoflurane being delivered from a vaporizer must be known exactly. As volatile anaesthetics differ in their physical properties, only vaporizers specifically calibrated for sevoflurane must be used. The administration of general anaesthesia must be individualized based on the patient's response. Hypotension and respiratory depression increase as anesthesia is deepened.

CONTRAINDICATIONS

מהות השינוי:

Sevoflurane should not be used in patients with known or suspected sensitivity to sevoflurane or to other halogenated inhalational anesthetics (e.g. history of hepatotoxicity, usually including elevated liver enzymes, fever, leukocytosis and/or eosinophilia temporally related to anesthesia with one of these agents).

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WARNINGS

מהות השינוי:

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).
~~Isolated reports of QT prolongation, very rarely associated with torsade de pointes (in exceptional cases, fatal), have been received. Caution should be exercised when administering sevoflurane to susceptible patients~~.

Isolated cases of ventricular arrhythmia were reported in pediatric patients with Pompe's disease.

Caution should be exercised in administering general anesthesia, including sevoflurane, to patients with mitochondrial disorders.

Malignant Hyperthermia

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

Treatment of malignant hyperthermia includes discontinuation of triggering agents (e.g. sevoflurane) administration of intravenous dantrolene sodium (Consult prescribing information for dantrolene sodium intravenous for additional information on patient management.), and application of supportive therapy. Such therapy includes vigorous efforts to restore body temperature to normal, respiratory and circulatory support as indicated, and management of electrolyte-fluid-acid-base abnormalities ~~Consult prescribing information for dantrolene sodium intravenous for additional information on patient management).~~

PRECAUTIONS

מהות השינוי:

Inducers of CYP2E1

Medicinal products and compounds that increase the activity of cytochrome P450 isoenzyme CYP2E1, such as isoniazid and alcohol, may increase the metabolism of sevoflurane and lead to significant increases in plasma fluoride concentrations (see PHARMACOLOGIC PROPERTIES, *Pharmacokinetics*, *Metabolism*). Concomitant use of sevoflurane and isoniazid can potentiate the hepatotoxic effects of isoniazid.

Hepatic Function

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

Labor and Delivery

Sevoflurane, like other inhalational agents, has relaxant effects on the uterus with the potential risk for uterine bleeding. Clinical judgment should be observed when using sevoflurane during obstetric anesthesia.

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Nursing Mothers

It is not known whether sevoflurane or its metabolites is excreted in human milk. Due to the absence of documented experience, women should be advised to skip breast-feeding for 48 hours after administration of sevoflurane and discard milk produced during this period.
~~The concentrations of sevoflurane in milk are probably of no clinical importance 24 hours after anesthesia. Because of rapid washout, sevoflurane concentrations in milk are predicted to be below those found with many other volatile anesthetics~~

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

מהות השינוי:

Patients should be advised that performance of activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, may be impaired for some time after general anesthesia (see WARNINGS AND PRECAUTIONS).

ADVERSE REACTIONS

מהות השינוי:

Post-Marketing Adverse Events – Other

- ~~Rare~~ reports of hypersensitivity (including contact dermatitis, rash, dyspnoea, 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).
- dystonia

העלון המעודכן לרופא נשלח למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, AbbVie Biopharmaceuticals Ltd., רחוב החרש 4, הוד השרון או בטלפון 7909600 – 09.

בברכה,

נעמי רביב

רוקחת ממונה

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