Sevoflurane Baxter

Inhalation Anaesthetic

Why partner with the "**inventor**[1] of sevoflurane ?

Baxter

History of Development

Baxter the "inventor" of sevoflurane (late 1960's)

1960 | 1970 | 1980 | 1990 | 2000 | 2010

1960s: Neil Armstrong first step on the moon (1969)

1970s: Baxter patented **sevoflurane** molecule and its use as an anaesthetic (1972)[1]

1980s: Baxter isoflurane (**AErrane**) FDA approval/ launch (1979)

1980s: Baxter patented **sevoflurane** « **one-step** » manufacturing process (1981)[3]

1980s: Baxter licenses Maruishi under Baxter **sevoflurane** patents (late 1980s')

1990: Maruishi launched **sevoflurane** in Japan (1990)

1990: Maruishi sub-licenses Abbott under Baxter **sevoflurane** patents (1992)

1990: **Suprane** FDA approval/ launch (1992)

1990s: Abbott launched **sevoflurane** worldwide (1995)

2000: Baxter patented **sevoflurane** « **three-step** » manufacturing process (1999)[4]

2000: **Sevoflurane Baxter** FDA approval (2002)

2010: **Sevoflurane Baxter** launch (Dec. 2005)

Sevoflurane was invented at Baxter

Sevoflurane was originally invented by B. Regan of Baxter and co-workers in the late 1960's and was patented in 1972.[1]

2 sevoflurane manufacturing processes were developed at Baxter and patented. For years, Abbott sevoflurane was manufactured under license from Baxter.[2]

- Further development work was done on the compound, including work on a « one-step » manufacturing process patented by Baxter in 1981.[3]
- In the late 1990's, Baxter developed a different, unique « three-step » manufacturing process. Baxter also obtained patents on its « three-step » process for making sevoflurane.[4]

1. U.S. Patent Nos. 3683092 and 3689571
2. Baker et al. Anesth Analg 2007;104:1447-51
3. U.S. Patent Nos. 4250334 and 4469898; EP Patent No. 0042412
4. U.S. Patent No. 5886239; EP Patent No. 1277724

Inside the operating room and in the Pharmacy, **Baxter Sevoflurane, an unbreakable, light, ergonomically designed,[5] aluminum container :**

Side-to-Side compression test[9] 481.9 pounds (mean)

Top-to-Bottom compression test[9] 842.4 pounds (mean)

Offers reassurance and peace of mind

- More than 5 years market experience[6] with more than 35 million patients anaesthetized[7] in the world.
  Approved in more than 50 countries in the world with more than 20 countries in Europe.
  Therapeutically equivalent[2,8] to Abbott sevoflurane.
- Virtually unbreakable aluminum container limits the chance of hazards caused by leakage from crushed plastic containers or broken bottles.[9]
- Distinguishable aluminum container, easy to read label and tamper proof yellow cap minimizes the chance of errors.
- New vaporizers with modern filling systems.

Easy to Handle

- Light weight (empty bottle around 50 grams) is key for the hospital workers, for transportation and for waste handling.
- Small circumference allows for good handling and firm grip, less storage space on shelves is required.
- Available with removable and reusable leak resistant adapters[10,11] for vaporizers filling.
- The removable-reusable adapters easily allow for cleaning after accidental soiling from surgery without compromising the integrity of the actual product unlike those where the filling adapter is connected.

Adapter for GE Healthcare Tec 7 and Aladin2 cassette

Adapter for Dräger Vapor 2000 and DIVA cassette

5. Data on file at Baxter Healthcare Corp.
6. Launched in December 2005
7. Data on file at Baxter Healthcare Corp. (based on avg. 12 patients per bottle)
8. U.S. Food and Drug Administration, www.fda.gov
9. Data on file at Baxter Healthcare Corp.; DDL, Inc. Report # 511010 «Compression Testing of Bottles for Sevoflurane for the Baxter Healthcare Corporation»
10. GE Healthcare Quality Department correspondance December 2008
11. Dräger «to whom it may concern» letter April 2009

Don’t wait any longer to partner with Baxter, the ¨inventor¨ of sevoflurane

- A user friendly[12] designed container
- Brand new vaporizers provided
- A lengthy experience in the field of anaesthesia
- A unique supplier of all the 3 modern IA (sevoflurane, isoflurane and desflurane), more than 300 million patients anaesthetized in the world
- A reliable manufacturer and supplier, high standards
- Quality assurance and full Customer Services support
- A commitment for the future

12. Data on file at Baxter Healthcare Corp.

Abbreviated Summary of Product Characteristics Sevoflurane Baxter, 100%, inhalation vapour, liquid

Therapeutic Indications
Induction and maintenance of general anaesthesia in adults and children.

Contraindications
Known hypersensitivity to sevoflurane or other halogenated anaesthetics. History of unexplained moderate to severe hepatic dysfunction with jaundice, fever and eosinophilia after anaesthesia with sevoflurane. Known or suspected susceptibility to malignant hyperthermia.

Special Warning and Precautions for Use
Sevoflurane should be administered only by persons appropriately trained in the administration of general anaesthesia. All patients anaesthetised with sevoflurane should be constantly monitored, including electrocardiogram (ECG), blood pressure (BP), oxygen saturation and end tidal carbon dioxide (CO_2). Sevoflurane should be delivered via a vaporizer specifically calibrated for use with sevoflurane so that the concentration delivered can be accurately controlled. Hypotension and respiratory depression increase as anaesthesia is deepened.
During maintenance of anaesthesia, increasing the sevoflurane concentration results in dose-dependent decreases in blood pressure. An excessive reduction in blood pressure can be corrected by reducing sevoflurane concentration. Recovery from general anaesthesia should be assessed carefully before patients are discharged from the recovery room.
Particular care must be taken when selecting the dosage for hypovolaemic, hypotensive or weakened patients.
Since there is little experience regarding patients with impaired renal function (serum creatinine ≥ 1.5 mg/dl or 135 micromol/l) sevoflurane should be administered with caution to this group of patients; renal function should be monitored postoperatively.
Caution should be exercised in obstetric anaesthesia due to the relaxant effect of sevoflurane on the uterus and increase in uterine haemorrhage.
Repeated use should be approached with caution.
Maintenance of haemodynamic stability is important in order to avoid myocardial ischaemia in patients with coronary artery disease.
In patients at risk of elevations of intracranial pressure (ICP), Sevoflurane should be administered cautiously in conjunction with ICP-reducing procedures, such as hyperventilation.
In susceptible individuals, sevoflurane may trigger a skeletal muscle hypermetabolic state leading to high oxygen demand and the clinical syndrome known as malignant hyperthermia. Rare cases of malignant hyperthermia have been reported with the use of sevoflurane. Treatment includes discontinuation of triggering agents (e.g. sevoflurane), administration of intravenous dantrolene sodium, and application of supportive therapy. Renal failure may appear later, and urine production should be monitored and sustained if possible.
Dystonic movements, which disappear without treatment, are seen in children who have received sevoflurane for anaesthesia induction. The relationship to sevoflurane is uncertain.
Emergence is generally rapid following sevoflurane anaesthesia; therefore, patients may require early postoperative pain relief.
Rapid emergence in children may briefly evoke a state of agitation and hinder cooperation (in about 25% of anaesthetised children).
The use of Sevoflurane has been associated with seizures. The majority of these 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. In children, limitation of the depth of anaesthesia is therefore essential.
Rare cases have been reported of slight, moderate or serious post-operative liver dysfunction or hepatitis (with or without jaundice). Caution is recommended when sevoflurane is used in patients with underlying liver problems or those who are receiving treatment with medications known to cause liver dysfunction.
In patients who have experienced hepatic injury, jaundice, unexplained fever or eosinophilia after administration of other inhalation anaesthetics, it is recommended to avoid administration of sevoflurane if anaesthesia with intravenous medicinal products or regional anaesthesia is possible.
The exothermic reaction between sevoflurane and CO_2 absorbent lime is reinforced when the CO_2 absorbent lime is dried out.
Rare cases have been reported of extreme heat, smoke and/or spontaneous fire from the anaesthesia vaporiser during use of sevoflurane together with dried-out absorbent lime. An unexpected delay in increase of inspired concentration of sevoflurane or an unexpected decrease of inspired concentration of sevoflurane compared with the setting of the vaporiser may be a sign of overheating of the CO_2 absorbent lime bottle. If the treating physician suspects the CO_2 absorbent lime to be dried-out, this must be replaced before the administration of sevoflurane.

Undesirable Effects
Like other inhalational anaesthetics, sevoflurane can produce dose-dependent cardiac and respiratory depression. Most of the undesirable effects are mild to moderate in severity and transient in nature. Nausea and vomiting have been reported in the post-operative period – common symptoms following surgery under general anaesthesia – which may be due to the inhalational anaesthetic, other medicinal products administered during or after surgery, or the patient’s reaction to the operation.
Very common and common side effects are: agitation, somnolence, headache, dizziness, tremor, bradycardia, tachycardia, hypotension, cough, respiratory depression, laryngismus, nausea, vomiting, increased salivation, fever, chills, increased SGOT levels and hypothermia.

For the posology, incompatibilities and interactions please refer to the full Summary of Product Characteristics (SPC).
This medicinal product is subject to medical prescription.

Date of preparation of the abbreviated SPC: December 2010

Indications, contra-indications and warnings may vary from country to country, please always consult your local SPC.

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