Halocarbon Isoflurane

- Global Distribution
- Pioneer in Fluorinated Anesthetics
- 100 mL Bottle (6 per case)
- 250 mL Bottle (6 per case)
- Color Coded
- Meets USP and PhEur Specifications
- Produced by Halocarbon Products Corporation

With headquarters in River Edge, New Jersey, and a state-of-the-art manufacturing plant in North Augusta, South Carolina, USA, Halocarbon is one of the world’s leading producers of specialty fluorochemicals. Halocarbon is a pioneer in the development of inhalation anesthetics, including the world’s most popular anesthetic, sevoflurane.
 Isoflurane, USP
Liquid For Inhalation
Rx only

DESCRIPTION:
Isoflurane, USP, a nonflammable liquid administered by vaporizing, is a general inhalation anesthetic drug. It is 1-Chloro-2,2,2-trifluoroethyl difluoromethyl ether.

Isoflurane is a clear, colorless, stable liquid containing no additives or chemical stabilizers. Isoflurane has a mildly pungent, musty, ethereal odor. Samples stored in indirect sunlight in clear, colorless glass for five years, as well as samples directly exposed for 30 hours to a 2 amp, 115 volt, 60 cycle long wave U.V. light were unchanged in composition as determined by gas chromatography. Isoflurane in one normal sodium methoxide-methanol solution, a strong base, for over six months consumed essentially no alkali, indicative of strong base stability. Isoflurane does not decompose in the presence of soda lime (at normal operating temperature), and does not attack aluminum, brass, iron, or copper.

CONTRAINDICATIONS
Known sensitivity to isoflurane, or to other halogenated agents.
Known or suspected genetic susceptibility to malignant hyperthermia.

WARNINGS
Since levels of anesthesia may be altered easily and rapidly, only vaporizers producing predictable concentrations should be used. Hypotension and respiratory depression increase as anesthesia is deepened.

Increased blood loss comparable to that seen with halothane has been observed in patients undergoing abortions.

Isoflurane markedly increases cerebral blood flow at deeper levels of anesthesia. There may be a transient rise in cerebral spinal fluid pressure which is fully reversible with hyperventilation.

PRECAUTIONS
General: As with any potent general anesthetic isoflurane should only be administered in an adequately equipped anesthetizing environment by those who are familiar with the pharmacology of the drug and qualified by training and experience to manage the anesthetized patient.

Regardless of the anesthetics employed, maintenance of normal hemodynamics is important to the avoidance of myocardial ischemia in patients with coronary artery disease.

Isoflurane, like some other inhalational anesthetics, can react with desiccated carbon dioxide (CO2) absorbents to produce carbon monoxide, which may result in elevated levels of carboxyhemoglobin in some patients. Case reports suggest that barium hydroxide lime and soda lime become desiccated when fresh gases are passed through the CO2 absorber canister at high flow rates over many hours or days. When a clinician suspects that CO2 absorbent may be desiccated, it should be replaced before the administration of isoflurane.

As with other halogenated anesthetic agents, isoflurane may cause sensitivity hepatitis in patients who have been sensitized by previous exposure to halogenated anesthetics (see CONTRAINDICATIONS).

Information to Patients: Isoflurane, as well as other general anesthetics, may cause a slight decrease in intellectual function for 2 or 3 days following anesthesia. As with other anesthetics, small changes in moods and symptoms may persist for up to 6 days after administration.

Laboratory Tests: Transient increases in BSP retention, blood glucose and serum creatinine with decrease in BUN, serum cholesterol and alkaline phosphatase have been observed.

Drug Interactions: Isoflurane potentiates the muscle relaxant effect of all muscle relaxants, most notably nondepolarizing muscle relaxants, and MAC (minimum alveolar concentration) is reduced by concomitant administration of N2O. See CLINICAL PHARMACOLOGY.

Pregnancy Category C: Isoflurane has been shown to have a possible anesthetic-related fetotoxic effect in mice when given doses 6 times the human dose. There are no adequate and well-controlled studies in pregnant women. Isoflurane should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk.

Malignant Hyperthermia: In susceptible individuals, isoflurane anesthetics may trigger a skeletal muscle hypermetabolic state leading to high oxygen demand and the clinical syndrome known as malignant hyperthermia.

ADVERSE REACTIONS
Adverse reactions encountered in the administration of isoflurane are in general dose dependent extensions of pharmacophysioligic effects and include respiratory depression, hypotension and arrhythmias.

Shivering, nausea, vomiting and ileus have been observed in the postoperative period.

As with all other general anesthetics, transient elevations in white blood count have been observed even in the absence of surgical stress. See PRECAUTIONS for information regarding malignant hyperthermia and elevated carboxyhemoglobin levels.

During marketing, there have been rare reports of mild, moderate and severe (some fatal) post-operative hepatic dysfunction and hepatitis.

OVERDOSAGE
In the event of overdosage, or what may appear to be overdosage, the following action should be taken: Stop drug administration, establish a clear airway and initiate assisted or controlled ventilation with pure oxygen.

HOW SUPPLIED
Isoflurane, USP is available in unit packages of 100 mL (NDC 12164-002-10) and 250 mL (NDC 12164-002-25) amber colored bottles.

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