ISPAN*

Perfluoropropane (C_3F_8)

LIQUIFIED GAS UNDER PRESSURE
CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
NOTE: Do not use the contents after the expiration date printed on the cylinder label.

DESCRIPTION

ISPAN* Perfluoropropane (C_3F_8) is a liquified gas under pressure and is administered by injection into the vitreous cavity. It is Octafluoropropane (C_3F_8) from the Haloalkanes chemical family. The boiling point is -36.7°C (-34.1°F) and the vapor pressure at 20°C is 100 psig (pounds per square inch gauge). Perfluoropropane is clear and colorless with a faintly sweet odor. ISPAN* C_3F_8 purity: perfluoropropane (Octafluoropropane) 99.8% (minimum), air 1000 ppm (maximum), and perfluoropropene 10 ppm (maximum).

INDICATIONS

ISPAN* Perfluoropropane (C_3F_8) is a surgical aid for use in the treatment of uncomplicated retinal detachment by pneumatic retinopexy. It is used in the form of an intravitreal injection for selected retinal breaks and to aid in resorption of subretinal fluid. Associated measures used include transconjunctival and transcleral cryotherapy and laser photocoagulation.

CONTRAINDICATIONS

Proliferative vitreoretinopathy (PVR) greater than Stage C, the mental or physical inability to maintain the therapeutic position for 5 postoperative days, severe glaucoma with more than a minimum of field loss and a cup to disc ratio equal to or greater than 0.6; uveitis; severe peripheral retinal degeneration; and high altitude travel, included but not limited to airline travel.

MODE OF ACTION

During the healing phase, the surface tension of the gas can prevent further progression of the retinal detachment by holding the retina against the choroid and permitting the retinal pigment epithelial pump to remove the subretinal fluid. The perfluoropropane diffuses from the eye in approximately 6 to 8 weeks.

WARNINGS

Use of Nitrous Oxide (N_2O) must be stopped at least 10 minutes before gas injection to ensure an adequate postoperative bubble is achieved. **Do not administer Nitrous Oxide (N_2O) if a gas bubble is present.** Nitrous Oxide (N_2O) rapidly partitions into the gas bubble causing expansion and a pressure increase in the eye that has been known to result in vision decrease and blindness. There is a risk of cataract formation if the lens is inadvertently damaged by the needle during gas injection during pneumatic retinopexy.

Acute rises in intraocular pressure (IOP) which threaten ocular blood flow for greater than 10 minutes should be controlled with paracentesis of aqueous fluid or removal of part of the gas bubble. Patients with compromised ocular blood flow such as those with severe diabetic retinopathy or ocular ischemia are at greater risk of vascular occlusion following the use of an expansile gas bubble. The intraocular pressure (IOP) should be checked by an experienced surgeon with either tactile touch or applanation tonometry when ISPAN* C_3F_8 is in place. Schiotz tonometry will give false low values compared to the true IOP.

Patient positioning following intravitreal gas injection is of great importance. The bubble must be properly situated with the proper positioning to allow contact of the gas bubble against the retinal hole or holes internally. Prone or seated face down positioning can prevent protracted contact between the gas bubble and the lens to avert a posterior subcapsular cataract, as well as to prevent pressure on the ciliary body and iris, and to prevent pupillary block in aphakic patients, which might increase intraocular pressure. The central retinal artery should be monitored during and after gas injection. Administration of systemic carbonic anhydrase inhibitors or topical glaucoma medications may be given for less severe elevations of intraocular pressure.

- Air travel is contraindicated until the gas bubble has completely dissipated. Normal cabin pressure changes will cause a severe enlargement of the gas bubble with a resultant increase in IOP. [1, 2]
- Patients should not travel through high elevations and over mountain ranges until the gas bubble has dissipated.[3]
- Patients should not receive hyperbaric oxygen therapy until the gas bubble has dissipated.[4]
- Patients should not receive Nitrous Oxide (N_2O) until the gas bubble has dissipated, as it will partition into the bubble and severely raise the IOP.
- Patients should not inhale ISPAN* C_3F_8 Gas in high concentration as suffocation may occur.

In order to assist with communication, a patient information card and bracelet are provided with this product and should be given to the patient prior to discharge from their eye surgery. The patient card is a convenient way to remind the patient about the important restrictions noted above, including limitations on the use of Nitrous Oxide (N_2O) in subsequent surgical or dental procedures; travel in an airplane or through high elevations; and when to remove the bracelet. The bracelet is to be worn by the patient to alert subsequent health professionals that the patient may have a gas bubble in their eye and to confer with the ophthalmologist prior to treating the patient. **Ensure both sides of the bracelet and card are completed and reviewed with the patient. Additional cards and bracelets may be obtained from Escalon Customer Service at 1-800-433-8197, or your local Escalon representative.**
Reorder: Hospital bracelets – TR9137; Patient Cards – TR9138

1. Lincoff, H, Weinberger, D, Reppucci, V, Lincoff, A: Air travel with intraocular gas. I. The mechanisms for compensation. Arch Ophthalmol 107:902-906, 1989
2. Lincoff, H, Weinberger, D, and Stergiu, P: Air travel with intraocular gas. II. Clinical considerations, Arch Ophthalmol 107:907-910, 1989
3. Hanscom, TA, and Diddie, KR: Mountain travel and intraocular gas bubbles, Am J Ophthalmol 104:546, 1987
4. Jackman, SV, and Thompson, JT: Effects of hyperbaric exposure on eyes with intraocular gas bubbles, Retina 15:160-166, 1995

PRECAUTIONS

Caution should be used in eyes with angle recession, pigment dispersion syndrome, significant anterior synechiae, traumatized eyes and eyes with significant vitreous hemorrhage obscuring an adequate view of the peripheral retina.

Sterile surgical techniques should be used for injection of ISPAN* C_3F_8. Blepharitis or other lid infections should be treated as if for intraocular surgery prior to using ISPAN* C_3F_8 for pneumatic retinopexy. Endophthalmitis has been reported rarely following pneumatic retinopexy.

There are no known teratogenic effects of ISPAN* C_3F_8 when injected into the eye. Until such information is available, it should be used with caution in pregnant women.

Sterility cannot be assured when the gas is transferred from the tank to a sterile syringe. The gas must be filtered through a sterile 0.22 µm filter prior to injection into the eye and used immediately. A pressure reducing gas regulator should be used to remove ISPAN* C_3F_8 from the cylinder. The delivery pressure of the gas should not exceed 10 psig. The lecture bottle stand is recommended for maintaining the necessary upright position of the gas cylinder during use. Close cylinder valve when not in use.

ADVERSE REACTIONS

Operative complications associated with pneumatic retinopexy using ISPAN* C_3F_8 may include:

- central retinal artery occlusion,
- anterior hyaloid gas injection,
- detachment of the pars plana epithelium,
- anterior lens touch,
- choroidal detachment,
- subconjunctival gas,
- vitreous hemorrhage,
- small subretinal gas bubble,
- subretinal hemorrhage,
- hyphema,
- escape of gas through the injection site, and
- elevated IOP which may require anterior chamber paracentesis or vitreous tap to reduce pressure

Postoperative complications associated with pneumatic retinopexy using ISPAN* C_3F_8 may include:

- severe elevated IOP that has been known to result in vision decrease and blindness if Nitrous Oxide (N_2O) is administered during a subsequent surgical or dental procedure with a gas bubble present in the eye,
- endophthalmitis,
- choroidal detachment,
- malignant glaucoma,
- cataract,
- mild premacular membrane,
- moderate macular pucker,
- proliferative vitreoretinopathy (PVR),
- retinal break reopened,
- new retinal detachment,
- new or missed retinal breaks,
- subconjunctival gas,
- subconjunctival hemorrhage,
- subretinal hemorrhage,
- vitreal pigmentation (known as "tobacco dust", frequently occurs due to cryosurgery and not because of gas injection),
- vitreous floaters,
- subretinal gas,
- uveitis,
- extrafoveal subretinal pigment migration,
- pigment in the macula, macular hole and
- increased anterior chamber cells/flare.

DIRECTIONS FOR USE

ISPAN* C_3F_8 is injected transconjunctivally and transclerally into the vitreous liquid.

Prior to pneumatic retinopexy with ISPAN* C_3F_8, it is common practice to decrease intraocular pressure to about 4 mmHg or less. Disinfect the injection site with several drops of sterile 5% Povidone-Iodine solution.

Place the ISPAN* C_3F_8 cylinder in a lecture bottle stand and attach the pressure reducing regulator. The delivery pressure of the gas should not exceed 10 psig. The ISPAN* C_3F_8 must be filtered through a sterile 0.22 µm filter into a sterile syringe that is to be used immediately. The globe is positioned so the injection site is uppermost and distant from the retinal tear. Inject the gas briskly transconjunctivally and transclerally about 4 mm posterior to the limbus into the vitreous liquid. The position of the needle tip is usually monitored by an assistant during this process. An average of 0.3 mL of 100% gas is injected. When the needle is withdrawn, the needle track is immediately blocked with a sterile cotton tipped applicator and the head rotated to position the bubble away from the injection site.

A bubble of ISPAN* C_3F_8 increases in volume by 4x in 72 hours. It is usually not necessary to reinject additional gas because the duration of perfluoropropane is approximately six to eight weeks. If the gas tamponade is not effective, it may be necessary to utilize alternative procedures, e.g. scleral buckling, laser photocoagulation, etc.

Following use of this product and prior to discharge, warn the patient of the following information present on the Patient Warning Card and Bracelet:

- Advise any health care provider about possible loss of vision or blindness if Nitrous Oxide (N_2O) anesthesia is administered with a gas bubble present in the eye.
- Not to travel by plane, through high elevations or over mountain ranges until the gas bubble has dissipated. Changes in elevation may cause the IOP to increase, which may cause loss of vision or blindness.
- Maintain proper head positioning following eye surgery. Incorrect head positioning may cause the surgery to be unsuccessful, glaucoma and cataracts.

HOW SUPPLIED

UNIT WEIGHT	UNIT VOLUME (at normal atmospheric pressure & temperature)	REF:
20 grams	2.5 liters	TR9089

Cylinder pressure at time of purchase: 100 psig (pounds per square inch gauge) at 20°C (68°F).

PURITY: 99.8% Perfluoropropane

STORAGE: Store at room temperature 15°-30°C (59°-86°F). ISPAN* C_3F_8 contains no additives. Do not use beyond the expiration date. Close cylinder valve when not in use.

ISPAN™ C_3F_8 gas is a fluorinated greenhouse gas covered by the Kyoto Protocol and has a Global Warming Potential (GWP) of 8,600. Residual ISPAN™ C_3F_8 gas should be recovered by appropriately qualified personnel and recycled, reclaimed or destroyed in accordance with local ordinances.

CAUTION: CONTENTS UNDER PRESSURE

Can cause rapid suffocation. Do not puncture. Do not store or use near heat or open flame. Use only with a pressure reducing gas regulator in an upright position. Close valve when not in use.

DO NOT INCINERATE.

Manufactured for:

ESCALON®

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Printed in U.S.A. 0305BI4963ESLD1 94174-4C