**Lumason**

**Lumason** (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use

**INDICATIONS AND USES**

Lumason is an ultrasound contrast agent indicated for:

- Ultrasonography of the liver in adults.
- Ultrasonography of the liver in pediatric patients.
- Ultrasonography of the urinary tract for the evaluation of bladder, ureters, and kidneys.

**WARNINGS AND PRECAUTIONS**

- Cardiopulmonary reactions, including fatalities. Always be prepared to treat patients who have experienced cardiopulmonary reactions:
  - After Lumason administration, continue filling the bladder with 0.9% Sodium Chloride Injection, USP until the injection line (20G) and administer as directed under the Administration Instructions.
  - Perform continuous alternate ultrasound imaging of the bladder, ureters, and kidneys during ultrasonography of the urinary tract.

**DOSAGE AND ADMINISTRATION**

**Pediatric Patients**: The recommended dose of Lumason after reconstitution is 2 mL administered as an intravenous bolus injection during ultrasonography of the liver. During a single examination, a second injection of 2.4 mL may be administered, if needed.

**Adults**: The recommended dose of Lumason after reconstitution is 2 mL administered as an intravenous bolus injection during ultrasonography of the liver. During a single examination, a second injection of 0.03 mL per kg may be administered, if needed. Refer to Section 2.3.1 for instructions for using the single patient use kit with diluent provided.

**Bladder Volume Calculation**: The total bladder volume in adults is calculated as [age in years + 2] x 0.4, up to a maximum of 2 mL per injection. The total bladder volume in children is calculated as [age in years + 0.4], up to a maximum of one third or half of its predicted total volume. The total bladder volume in children is calculated as [age in years + 2] x 0.4, up to a maximum of 2 mL per injection.

**CONTRAINDICATIONS**

Lumason is contraindicated in patients with known or suspected:

- Hypersensitivity to sulfur hexafluoride or any of its components.

**ADVERSE REACTIONS**

The most common adverse reactions are:

- Headache
- Nausea

Other adverse reactions include:

- Hypersensitivity reactions
- Cardiopulmonary reactions
- Bladder spasms
- Chest discomfort
- Feeling hot

**PRESCRIBING INFORMATION**

**NONCLINICAL TOXICOLOGY**

None available.

**CLINICAL STUDIES**

A total of 79% subjects were White; 4% were Black; 16% were Asian; <1% were Hispanic; and <1% were in other racial categories. The following serious adverse reactions are discussed elsewhere in the labeling:

- Headache
- Nausea

**ADDITIONAL INFORMATION**

- Contents of Lumason Kit
  - Twenty Mini-Spikes
  - One Mini-Spike
  - Two Glass vials
  - One Eurobid vial
  - One Frontero P. Reflex Blue U
  - One Correction in Picture

- Usage of UltraMicro Contrast®:
  - UltraMicro Contrast® is a sulfur hexafluoride lipid-type A microsphere (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use.
  - UltraMicro Contrast® is indicated for ultrasonography of the liver in adults.
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**FULL PRESCRIBING INFORMATION: CONTENTS**

This highlights do not include all the information available in the full prescribing information.

- Please refer to the full prescribing information for detailed information on the indications, contraindications, warnings, precautions, adverse reactions, and precautions for use.

**CLINICAL PHARMACOLOGY**

- Pharmacokinetics
- Metabolism
- Distribution
- Excretion

**REFERENCES**

- Clinical studies
- Nonclinical toxicology
- Pharmacology
- Pharmacokinetics

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ed doses, concentrations of SF6 in blood peaked within 1 to 2 minutes for both doses. The terminal half-life of SF6 in blood following intravenous administration is eliminated via the lungs. In a clinical study that evaluated the SF6 component of Lumason, the mean values for the apparent steady-state volume of distribution of SF6 following intravenous administration, were 341 mcL and 710 mcL for Lumason doses of 0.03 mL/kg and 0.3 mL/kg, respectively. Preferential uptake of SF6 was noted in the liver, and any potential adverse effects on the liver have not been observed in clinical studies. The results of these studies support the conclusion that SF6 is not harmful to the liver.

Distribution

Each milliliter of reconstituted Lumason suspension contains 1.5 to 5.6 x108 microspheres, 68 mcg SF6 (12 mcL), 0.038 mg of palmitic acid. The headspace of each vial contains 6.07 mg/mL (± 2 %) sulfur hexafluoride, SF6, or 60.7 mg per vial. Of the total number of 6856 adult patients in clinical studies of Lumason, 39% were 65 and over, while 11% were 75 and over years).

Safety and effectiveness in pediatric patients has been established for use in ultrasonography of the urinary tract for the detection and evaluation of hydronephrosis. Pediatric patients, aged 1 month to 17 years (mean 1.83 mL). There were 7 female, 10 white, and 2 black patients.

Endocardial Border Delineation

In a study of healthy subjects, the mean values for the apparent steady-state volume of distribution of SF6 following intravenous administration were 341 mcL and 710 mcL for Lumason doses of 0.03 mL/kg and 0.3 mL/kg, respectively. Preferential uptake of SF6 was noted in the liver, and any potential adverse effects on the liver have not been observed in clinical studies. The results of these studies support the conclusion that SF6 is not harmful to the liver.

In ultrasonography of the urinary tract, Lumason facilitates the detection of reflux of fluid from the bladder into the ureters. In Study B, 30 patients (15 male, 15 female, mean age 56.0 years) underwent voiding urosonography (VUS). Patients were also evaluated with voiding cystourethrography (VCUG) as the reference standard. Out of 71 reference standard positive images, Lumason ultrasonography was positive in 57 and falsely negative in 5. The sensitivity and specificity of Lumason ultrasonography were 80.3% (95% CI: 67.7-90.2) and 97.6% (95% CI: 90.7-99.2), respectively.

In studies with normal kidneys, Lumason was found to provide a marked increase in echogenicity with enhanced delineation of the renal pelvic calices, renal sinus fat, and the cortex. The contrast enhancement following intravenous administration is eliminated via the lungs. In a clinical study that evaluated the SF6 component of Lumason, the mean values for the apparent steady-state volume of distribution of SF6 following intravenous administration, were 341 mcL and 710 mcL for Lumason doses of 0.03 mL/kg and 0.3 mL/kg, respectively. Preferential uptake of SF6 was noted in the liver, and any potential adverse effects on the liver have not been observed in clinical studies. The results of these studies support the conclusion that SF6 is not harmful to the liver.

In one published study, 44 patients with an indeterminate focal liver lesion (23 males, 21 females, age range: 4-18 years, 14 CLINICAL STUDIES

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