**INDICATIONS AND USAGE**

Lumason (sulfur hexafluoride lipid-type A microspheres) is indicated for use in ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux and in ultrasonography of the urinary tract for the evaluation of urinary tract stones. Lumason is also indicated for use in ultrasonography of the liver in adults and for use in pediatric patients 1 year of age and older to evaluate liver lesions.

**CONTRAINDICATIONS**

Contraindications to Lumason include:

- Hypersensitivity reactions (5.2)
- History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in Lumason
- History of hypersensitivity reactions (5.2) to components of the lipid-type A microsphere (pentadecyl-dimethylammonium bromide)
- Children under the age of 1 year (see Warnings and Precautions), as the safety and effectiveness of Lumason in this age group have not been studied.
- Use in neonates (see Warnings and Precautions).

**WARNINGS AND PRECAUTIONS**

- Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following the administration of ultrasound contrast agents. The reported reactions that may follow the administration of ultrasound contrast agents include: fatal cardiac or respiratory arrest, dysrhythmias, hypotension, ventricular fibrillation, cardiac standstill, pulmonary hypertension, anaphylaxis, other respiratory events (including respiratory distress, dyspnea, sudden death), cerebral events (intracranial or cerebral hemorrhage, stroke), and cardiovascular events (cardiac arrest, sudden death, myocardial infarction, shock, angina pectoris).

- Serious adverse reactions in adults have occurred uncommonly during or shortly following the administration of ultrasound contrast agents, including deaths. These reactions typically occurred within 30 minutes of injection of the ultrasound contrast agent and have included cardiac death, cardiac arrest, pulmonary and cerebral edema, stroke, dysrhythmias, hypotension, respiratory failure, cardiac standstill, anaphylaxis, and anaphylactic shock. In pediatric patients, serious adverse reactions have occurred uncommonly during or shortly following the administration of ultrasound contrast agents, including deaths. These reactions typically occurred within 30 minutes of injection of the ultrasound contrast agent and have included cardiac arrest, sudden death, ventricular fibrillation, cardiac standstill, hypotension, dysrhythmias, and anaphylaxis.

- Lumason is contraindicated in patients with a history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in Lumason.

**ADVERSE REACTIONS**

- In adults, the most common adverse reactions associated with the use of Lumason in the context of ultrasound examination were headache and nausea. These adverse reactions were reported in 6.1% of patients. The most common adverse reactions associated with the use of Lumason in the context of echocardiography were headache and nausea. These adverse reactions were reported in 2.1% of patients.

- In pediatric patients, the most common adverse reactions associated with the use of Lumason in the context of ultrasound examination were headache and nausea. These adverse reactions were reported in 4.6% of patients. The most common adverse reactions associated with the use of Lumason in the context of echocardiography were headache and nausea. These adverse reactions were reported in 3.1% of patients.

- In pregnant women, the most common adverse reactions associated with the use of Lumason were headaches and nausea. These adverse reactions were reported in 5.1% of patients.

**DOSAGE AND ADMINISTRATION**

- **Ultrasonography of the Liver**

  - **Ultrasonography of the Liver in Adults:** After reconstitution, administer 0.03 mL per kg as needed to use LUMASON.
  - **Ultrasonography of the Liver in Pediatric Patients:** After reconstitution, administer 0.01-0.03 mL per kg as needed to use LUMASON.

- **Ultrasonography of the Urinary Tract**

  - **Echocardiography:** After reconstitution, administer 0.03 mL per kg as needed to use LUMASON.

- **Administration Instructions**

  - **Ultrasonography of the Liver in Adults:** After reconstitution, administer 0.03 mL per kg as needed to use LUMASON.

  - **Ultrasonography of the Liver in Pediatric Patients:** After reconstitution, administer 0.01-0.03 mL per kg as needed to use LUMASON.

**PREGNANCY**

- **Pregnancy Category C**

- **Lactation**

- **Teratogenic Effects**

- **Nonteratogenic Effects**

- **Human Pharmacology**

- **Data from animal studies**

- **Data from human studies**

- **Clinical studies**

- **INDICATIONS AND USAGE**

  - **Ultrasound Contrast Indications:**

    - **Liver Imaging:** Lumason is indicated for use in ultrasonography of the liver in adults.
    - **Liver Imaging in Pediatric Patients:** Lumason is indicated for use in ultrasonography of the liver in pediatric patients.
    - **Kidney and Bladder Imaging:** Lumason is indicated for use in ultrasonography of the urinary tract in adults and pediatric patients.
    - **Kidney and Bladder Imaging in Pediatric Patients:** Lumason is indicated for use in ultrasonography of the urinary tract in pediatric patients.

- **CONTRAINDICATIONS**

  - **Hypersensitivity to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in Lumason**
  - **History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in Lumason**
  - **Children under the age of 1 year**
  - **Use in Neonates**

- **WARNINGS AND PRECAUTIONS**

  - **Serious Cardiopulmonary Reactions:** Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following the administration of ultrasound contrast agents. The reported reactions that may follow the administration of ultrasound contrast agents include: fatal cardiac or respiratory arrest, dysrhythmias, hypotension, ventricular fibrillation, cardiac standstill, pulmonary hypertension, anaphylaxis, other respiratory events (including respiratory distress, dyspnea, sudden death), cerebral events (intracranial or cerebral hemorrhage, stroke), and cardiovascular events (cardiac arrest, sudden death, myocardial infarction, shock, angina pectoris).

  - **Serious Adverse Reactions:** Serious adverse reactions in adults have occurred uncommonly during or shortly following the administration of ultrasound contrast agents, including deaths. These reactions typically occurred within 30 minutes of injection of the ultrasound contrast agent and have included cardiac death, cardiac arrest, pulmonary and cerebral edema, stroke, dysrhythmias, hypotension, respiratory failure, cardiac standstill, anaphylaxis, and anaphylactic shock. In pediatric patients, serious adverse reactions have occurred uncommonly during or shortly following the administration of ultrasound contrast agents, including deaths. These reactions typically occurred within 30 minutes of injection of the ultrasound contrast agent and have included cardiac arrest, sudden death, ventricular fibrillation, cardiac standstill, hypotension, dysrhythmias, and anaphylaxis.

  - **Serious Cardiopulmonary Reactions:** Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following the administration of ultrasound contrast agents. The reported reactions that may follow the administration of ultrasound contrast agents include: fatal cardiac or respiratory arrest, dysrhythmias, hypotension, ventricular fibrillation, cardiac standstill, pulmonary hypertension, anaphylaxis, other respiratory events (including respiratory distress, dyspnea, sudden death), cerebral events (intracranial or cerebral hemorrhage, stroke), and cardiovascular events (cardiac arrest, sudden death, myocardial infarction, shock, angina pectoris).

  - **Serious Adverse Reactions:** Serious adverse reactions in adults have occurred uncommonly during or shortly following the administration of ultrasound contrast agents, including deaths. These reactions typically occurred within 30 minutes of injection of the ultrasound contrast agent and have included cardiac death, cardiac arrest, pulmonary and cerebral edema, stroke, dysrhythmias, hypotension, respiratory failure, cardiac standstill, anaphylaxis, and anaphylactic shock. In pediatric patients, serious adverse reactions have occurred uncommonly during or shortly following the administration of ultrasound contrast agents, including deaths. These reactions typically occurred within 30 minutes of injection of the ultrasound contrast agent and have included cardiac arrest, sudden death, ventricular fibrillation, cardiac standstill, hypotension, dysrhythmias, and anaphylaxis.
3.2 Pulmonary Impairment: Pharmacokinetics in Specific Populations

In a study of patients with pulmonary impairment, blood concentrations of SF₆ peaked at 1 to 4 minutes following Lumason administration. The mean cumulative recovery of SF₆ in these patients was 85% of the injected dose at 20 minutes following injection, compared to 90% in healthy subjects. No significant differences in pharmacokinetics were observed between patients with pulmonary impairment and healthy subjects.

3.3.10 Metabolism

The metabolic fate of Lumason is not known. It is likely that Lumason is not metabolized in the body, as it is a gas and is excreted unchanged in the urine and feces. The elimination half-life of Lumason has not been determined in humans.

4. CLINICAL PHARMACOLOGY

4.1 Mechanisms of Action

The mechanism of action of Lumason is based on the fact that ultrasound contrast media are sonicated by high-intensity ultrasound and the resulting microbubbles collapse, releasing energy in the form of a transient local heating effect. This effect can be observed as an increase in the intensity of the ultrasound signal, which is recorded as a change in brightness on the ultrasound image.

4.2 Pharmacokinetics

The pharmacokinetics of Lumason have been studied in healthy adult subjects and in patients with pulmonary impairment. In healthy adult subjects, the mean time for peak concentration of SF₆ in the blood was 1 to 3 minutes following injection, and the mean cumulative recovery of SF₆ at 20 minutes was 90% of the injected dose.

4.3 Pharmacodynamics

The pharmacodynamic effects of Lumason are related to its ability to enhance the signal intensity of the microvasculature. This effect is observed as an increased blood flow signal intensity, which is recorded as a change in the brightness of the ultrasound image.

4.4 Special Populations

4.4.1 Pregnancy

Lumason is not expected to cause harm to the developing fetus. It is recommended that the benefits of using Lumason during pregnancy outweigh any potential risks.

4.4.2 Nursing Mothers

It is unknown if Lumason is excreted in breast milk. Because of the potential for serious adverse events, mothers should not breastfeed their infants if Lumason is administered.

4.4.3 Pediatric Patients

Lumason is approved for use in children 2 years of age and older.

4.5.5 Geriatric Use

No specific studies have been conducted in patients 65 years of age and older. However, the pharmacokinetics of Lumason have been studied in healthy elderly subjects (ages 65 to 85) and in patients with pulmonary impairment. No significant differences in pharmacokinetics were observed between these populations and healthy adult subjects.

5.1 Adverse Reactions

The most common adverse reactions reported with the use of Lumason are injection site reactions, such as pain, redness, and swelling. Other adverse reactions include dyspnea, chest pain, and wheezing. These reactions are usually mild and transient.

5.2 Precautions

Precautions include monitoring for evidence of anaphylaxis, especially in patients with a history of anaphylaxis to other agents, and ensuring that adequate medical personnel and equipment are available to manage anaphylaxis.

6.1 How Supplied

The use of Lumason is via an injection of a mixture of SF₆ and perfluorocarbon-based contrast media. The device is supplied as a single-use kit containing a glass vial of Lumason reconstituted solution, a syringe, and a needle.

6.2储放条件和有效期

The reconstituted Lumason solution should be stored at room temperature and used within 24 hours of reconstitution. The shelf life of the reconstituted solution is 2 years from the date of manufacture.

7.6.1 Ultrasonography of the Liver

Lumason was included in two studies of ultrasound-guided biopsy in the liver. In these studies, Lumason was administered to patients with suspected liver lesions, and the biopsy was performed using an ultrasound-guided needle. The results showed that Lumason significantly increased the diagnostic accuracy of needle biopsy in the liver.

8.1.1.3 Pulmonary Impairment

In patients with pulmonary impairment, the mean cumulative recovery of SF₆ at 20 minutes following Lumason injection was 85% of the injected dose, compared to 90% in healthy subjects. No significant differences in pharmacokinetics were observed between patients with pulmonary impairment and healthy subjects.