LUMASON
(sulfur hexafluoride lipid-type A microspheres) prescribing information, for Injectable Suspended for Intravesical Use or Intravenous Use

WARNINGS: SERIOUS CARDIOPULMONARY REACTIONS
Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of sulfur hexafluoride lipid microspheres [see Warnings and Precautions (5.1)]. Most serious reactions occur within 30 minutes of administration [see Warnings and Precautions (5.1)].

1. Infiltration or extravasation - A brief summary follows.

1.1 Intravascular Administration

- Use immediately after reconstitution. If the suspension is not used immediately after reconstitution, reassess the microspheres for a few seconds by hand agitation before the suspension is drawn into the syringe. Reconstituted suspension within a vial may be used for up to 3 hours from the time of its reconstitution. Maintain the vial containing the reconstituted suspension at room temperature.

2.4 Administration Instructions

Inspect visually for particulate matter and discoloration prior to administration. Whenever solution and container have been reconstituted, the suspension is milky-white, and does not contain visible particulate matter. Do not use the single-patient-use vial for more than one patient.

1. Intravenous Administration

- Administer LUMASON as an intravenous bolus injection.

2. Intravesical Administration in Pediatric Patients

- Intravesical administration is indicated in patients weighing less than 15 kg.

3. Ultrasonography of the Liver

- Ultrasonography of the liver in adult and pediatric patients to characterize focal liver lesions.

4. Ultrasonography of the Urinary Tract

- Ultrasonography of the urinary tract in pediatric patients for the evaluation of vesicoureteral reflux.

5. Echocardiography

- Echocardiography by intra-arterial injection [see Warnings and Precautions (5.2)].

Warnings and Precautions (5.1)

- Use LUMASON only after a thorough evaluation of suspected or known vesicoureteral reflux.

- Ultrasound of the liver in adult and pediatric patients to characterize focal liver lesions.

- Ultrasonography of the urinary tract in pediatric patients for the evaluation of vesicoureteral reflux.

- Ultrasonography of the liver.

- Echocardiography by intra-arterial injection.

- Use LUMASON only after a thorough evaluation of suspected or known vesicoureteral reflux.

- Ultrasonography of the urinary tract in pediatric patients for the evaluation of vesicoureteral reflux.

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