KNOW NOW with LUMASON for characterization of focal liver lesions in pediatric and adult patients

The individuals who appear are for illustrative purposes only. All persons depicted are models and not real patients. Ultrasound image is courtesy of Dr Ed Grant, Keck Hospital of USC; USC Norris Comprehensive Cancer Center; University of Southern California, Los Angeles, California. Individual results may vary.
APPROVED—LUMASON IS THE FIRST AND ONLY FDA-APPROVED ULTRASOUND CONTRAST AGENT INDICATED FOR USE IN PEDIATRIC AND ADULT PATIENTS TO CHARACTERIZE FOCAL LIVER LESIONS

LUMASON is known globally as SonoVue® which has been administered to millions of patients worldwide since its first approval in 2001.

INDICATIONS AND USAGE
LUMASON is an ultrasound contrast agent indicated for use:
- in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms
- in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients
- in ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients

CONTRAINDICATIONS
LUMASON is contraindicated in patients with:
- history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

IMPORTANT SAFETY INFORMATION
WARNING: SERIOUS CARDIOPULMONARY REACTIONS
Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of ultrasound contrast agents, including 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)].
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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Contrast enhanced ultrasound can reduce the number of indeterminate diagnoses with conventional ultrasound by > 50%.

Contrast enhanced ultrasound can:

- Effectively characterize benign and malignant hepatic lesions
- Assess blood flow dynamics
- Help reduce follow-up imaging tests

In ultrasonography of the liver, LUMASON provides dynamic patterns of differential signal intensity enhancement between focal liver lesions and liver parenchyma during the arterial, portal venous, and late phase of signal intensity enhancement of the microvasculature.

**Non-enhanced US**

**LUMASON**

<table>
<thead>
<tr>
<th>Arterial phase</th>
<th>Portal phase</th>
<th>Late phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
</tbody>
</table>

Contrast images shown are representative images. Individual results may vary.

Reprinted with permission from *World Journal of Gastroenterology*.5

36-year-old female.

A. 4.0 cm hypoechoic lesion B-mode sonography. **B.** LUMASON showed a peripheral enhancement with nodular contrast accumulations in the arterial phase. **C.** Slow progression of the enhancement from the periphery toward the center of the lesion, with a broader peripheral enhancement zone seen in the portal phase. **D.** During the late phase, the lesion is completely filled with contrast and appears hypoenhanced compared to the surrounding normal liver tissue. The enhancement pattern is typical for a hemangioma.

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Improved sensitivity and specificity with LUMASON contrast enhanced ultrasound compared to unenhanced ultrasound:¹

In 2 studies in adults (499 patients in total), images enhanced with LUMASON resulted in improved characterization of focal liver lesions compared to non-contrast enhanced ultrasound images.¹

**STUDY A**

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity (patients with malignant lesions); N=119</th>
<th>Specificity (patients with benign lesions); N=140</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>LUMASON %</td>
<td>Non-contrast %</td>
</tr>
<tr>
<td>Reader 1</td>
<td>87†</td>
<td>49</td>
</tr>
<tr>
<td>Reader 2</td>
<td>76†</td>
<td>35</td>
</tr>
<tr>
<td>Reader 3</td>
<td>92†</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>LUMASON %</td>
<td>Non-contrast %</td>
</tr>
<tr>
<td>Reader 4</td>
<td>65</td>
<td>53</td>
</tr>
<tr>
<td>Reader 5</td>
<td>61†</td>
<td>41</td>
</tr>
<tr>
<td>Reader 6</td>
<td>47</td>
<td>66</td>
</tr>
</tbody>
</table>

†Statistically significant improvement from non-contrast (P<0.05 based on McNemar’s test).

**STUDY B**

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity (patients with malignant lesions); N=124</th>
<th>Specificity (patients with benign lesions); N=116</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LUMASON %</td>
<td>Non-contrast %</td>
</tr>
<tr>
<td>Reader 4</td>
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**LUMASON demonstrated 98% specificity in 44 children aged 4 to 18 years with an indeterminate focal liver lesion.¹**

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Ultrasound contrast agents are typically safe with a very low incidence of side effects. It is not necessary to perform laboratory tests prior to LUMASON administration to assess liver or kidney function before their administration. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In the LUMASON completed clinical trials, 6856 adult patients were exposed to LUMASON; the most commonly reported adverse reactions (occurring in at least 0.2% of patients) are listed below.

Most adverse reactions were mild to moderate in intensity and resolved spontaneously.

<table>
<thead>
<tr>
<th>Number (%) of Patients with Adverse Reactions</th>
<th>Headache</th>
<th>Nausea</th>
<th>Dysgeusia</th>
<th>Injection-site pain</th>
<th>Feeling hot</th>
<th>Chest discomfort</th>
<th>Chest pain</th>
<th>Dizziness</th>
<th>Injection-site warmth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>340 (5%)</td>
<td>65 (1%)</td>
<td>37 (0.5%)</td>
<td>29 (0.4%)</td>
<td>23 (0.3%)</td>
<td>18 (0.3%)</td>
<td>17 (0.2%)</td>
<td>12 (0.2%)</td>
<td>11 (0.2%)</td>
</tr>
</tbody>
</table>

LUMASON characteristics:
LUMASON microspheres are composed of sulfur hexafluoride gas in the core and an outer shell monolayer of phospholipids that resists pressure changes.

- ≥99% of LUMASON microspheres are ≤10 µm
- 100% of LUMASON microspheres are ≤20 µm
- Sulfur hexafluoride gas in LUMASON is inert and undergoes little or no biotransformation; not to be confused with sulfa-based drugs

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The first and only FDA-approved ultrasound contrast agent for characterization of focal liver lesions

In liver ultrasonography, LUMASON helps you:

• Characterize focal liver lesions
• Assess dynamic patterns of differential signal intensity enhancement between focal liver lesions and liver parenchyma during 3 phases of liver enhancement
• Facilitate your workflow with LUMASON’s portable kit

To find out how Bracco Support can help enhance your insights, visit www.braccoimaging.com.

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LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by Bracco Suisse S.A., Plan-les-Ouates Geneve, Switzerland (LUMASON lyophilized powder vial-25 mg lipid-type A/60.7 sulfur hexafluoride gas); Vetter Pharma-Fertigung GmbH & Co. KG, 88212 Ravensburg, Germany (Sodium Chloride 0.9% Injection, USP); B. Braun Melsungen AG, 34212 Melsungen, Germany (Mini-Spike).

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