



EFSUMB

EUROPEAN FEDERATION OF SOCIETIES FOR ULTRASOUND IN MEDICINE AND BIOLOGY
'Building a European Ultrasound Community'

Guidelines and Good Clinical Practice Recommendations for Contrast Enhanced Ultrasound (CEUS) - - Update 2008

Appendix 1 (

SonoVue® (Bracco International B.V.)

Composition, Packaging and Storage:

Composition:

Sulphur hexafluoride microbubbles 8 microliters / ml

- Shell: phospholipids
- Gas: sulphur hexafluoride (SF₆)
- Excipients:

Powder: macrogol 4000, distearoylphosphatidylcholine, dipalmitoylphosphatidylglycerol sodium, palmitic acid

Solvent: sodium chloride 0.9% w/v solution for injection

Packaging:

- SonoVue® vial (containing 25 mg of lyophilised powder)
- Prefilled syringe (containing 5 ml sodium chloride 0.9% w/v solution for injection)
- Mini-Spike transfer system

Stability after reconstitution: 6 hours

Storage: no special precautions

Labeled Indications (EU)

Echocardiography

SonoVue® is a transpulmonary echocardiographic contrast agent for use in patients with suspected or established cardiovascular disease to provide opacification of cardiac chambers and enhance left ventricular endocardial border delineation.

Doppler of macrovasculature

SonoVue® increases the accuracy in detection or exclusion of abnormalities in cerebral arteries and extracranial carotid or peripheral arteries by improving the Doppler signal-to-noise ratio.

SonoVue[®] increases the quality of the Doppler flow image and the duration of clinically-useful signal enhancement in portal vein assessment.

Doppler of microvasculature

SonoVue[®] improves display of the vascularity of liver and breast lesions during Doppler sonography, leading to more specific lesion characterization.

Recommended Dose

B-Mode imaging of cardiac chambers, at rest or with stress: 2.0 ml

Vascular Doppler imaging: 2.4 ml

During a single examination, a second injection on the recommended dose can be made when deemed necessary by the physician.

Every injection should be followed by a flush with 5ml of sodium chloride 0.9% w/v solution for injection.

Contraindications

SonoVue[®] should not be administered to patients with known hypersensitivity to sulphur hexafluoride or to any of the components of SonoVue[®].

SonoVue[®] is contraindicated for use in patients with recent acute coronary syndrome or clinically unstable ischaemic cardiac disease including: evolving or ongoing myocardial infarction, typical angina at rest within last 7 days, significant worsening of cardiac symptoms within last 7 days, recent coronary artery intervention or other factors suggesting clinical instability (for example, recent deterioration of ECG, laboratory or clinical findings), acute cardiac failure, Class III/IV cardiac failure, or severe rhythm disorders.

SonoVue[®] is contraindicated in patients known to have right-to-left shunts, severe pulmonary hypertension (pulmonary artery pressure >90 mmHg), uncontrolled systemic hypertension, and in patients with adult respiratory distress syndrome. The safety and efficacy of SonoVue[®] have not been established in pregnant and lactating woman therefore, SonoVue[®] should not be administered during pregnancy and lactation.