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EPAR summary for the public

SonoVue

sulphur hexafluoride

This is a summary of the European public assessment report (EPAR) for SonoVue. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use SonoVue.

For practical information about using SonoVue, patients should read the package leaflet or contact their doctor or pharmacist.

What is SonoVue and what is it used for?

SonoVue is a medicine for diagnostic use only. It is a contrast agent (it helps make internal body structures visible during imaging tests). SonoVue is used in tests that measure how ultrasound travels within the body because it improves the ability to create an echo. It is only used when the results of the test without a contrast agent are inconclusive. SonoVue is used in:

- echocardiography (a diagnostic test where an image of the heart is obtained). It is used to obtain a clearer scan of the chambers of the heart, especially of the left ventricle, in adults with suspected or confirmed coronary artery disease;
- Doppler (a diagnostic test that measures the speed of blood flow). SonoVue can be used in adults for Doppler tests for large blood vessels, such as those in the head, those leading to the head or the main vein to the liver, or for smaller blood vessels such as those in lesions (areas of disease) in the breast or liver;
- ultrasound scans of the bladder and urinary tract in children and adolescents to detect vesicoureteral reflux, a condition in which urine flows backward from the bladder to the kidneys, leading to scarring and kidney infections.

The medicine contains the active substance sulphur hexafluoride (a gas).

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How is SonoVue used?

SonoVue can only be obtained with a prescription and should only be used by doctors who have experience in diagnostic ultrasound imaging. It is available as a kit including one vial of gas and powder and one pre-filled syringe containing 5 ml of solvent. When made up into a solution, SonoVue contains sulphur hexafluoride gas as 'microbubbles' in suspension in a liquid.

When used with ultrasound of the heart or for measuring blood flow, SonoVue is injected intravenously (into a vein) before the test is carried out, as a 2 or 2.4 ml dose depending on which test is being carried out. The dose can be repeated. When used to detect vesicoureteral reflux in children, 1 ml of SonoVue is given by a catheter into the bladder, which is then filled with saline (salt) solution until the patient feels the need to empty their bladder. The ultrasound scan of the bladder and kidneys is carried out during filling and emptying of the bladder.

How does SonoVue work?

The active substance in SonoVue, sulphur hexafluoride, is a gas that is not soluble in body fluids or water. When SonoVue is made up into a suspension, the gas is trapped in tiny bubbles called microbubbles. After injection, the microbubbles travel in the blood or disperse throughout the bladder, where they reflect ultrasound waves more than the surrounding tissues. This helps to enhance the results of tests that rely on measuring ultrasound. The gas is removed naturally from the blood through the lungs or passed out in the urine after bladder scans.

What benefits of SonoVue have been shown in studies?

For use in echocardiography, SonoVue was investigated in 3 main studies. These involved a total of 317 patients, and compared SonoVue with another contrast agent and placebo (a dummy treatment). SonoVue was more effective than the comparator and than placebo in improving the clarity of the image obtained of the left ventricle and left ventricle border.

For use in Doppler scans, a further 3 main studies involved 361 patients who were being tested for abnormalities in large blood vessels, and 217 patients being tested for abnormalities in smaller vessels. In these studies, SonoVue was not compared with any other medicine, but the results of the test with SonoVue were compared with the 'gold standard', such as angiography (X-rays of blood vessels). The main measure of effectiveness was how clear the images obtained in the test were. Using SonoVue to measure blood flow in large blood vessels improved the quality of the scan when testing the cerebral arteries (in the head), the carotids (in the neck) and the portal vein (leading to the liver), but not the renal arteries (leading to the kidneys). For the smaller vessels, SonoVue led to better quality scans when looking at the blood flow in breast and liver lesions. However, this was not observed in the pancreas, kidney, ovary or prostate gland.

The company also presented results from the literature of 4 main studies involving over 500 children given SonoVue before ultrasound scans of the bladder to detect vesicoureteral reflux. Ultrasound with SonoVue was compared with the standard method using X-rays with an X-ray contrast agent. Pooled analysis of the studies suggested that SonoVue identified children with vesicoureteral reflux in 89% of cases, and correctly distinguished patients who did not have the condition in 81% of cases. However, the results were not sufficient to state that a negative result following ultrasound with Sonovue allows the practitioner to exclude a diagnosis of vesicoureteral reflux.

What are the risks associated with SonoVue?

The most common side effects when SonoVue is injected into a vein (seen in up to 1 in 100 patients) are headache, nausea (feeling sick) and reactions at the injection site. No side effects attributable to the medicine have been reported in children given SonoVue into the bladder. For the full list of all side effects reported with SonoVue, see the package leaflet.

SonoVue must not be injected into a vein in patients known to have right-to-left shunts (abnormal movement of blood within the heart), severe pulmonary hypertension (high blood pressure in the pulmonary artery, the blood vessel that leads from the heart to the lungs), uncontrolled hypertension (high blood pressure) or adult respiratory distress syndrome (severe fluid build-up in both lungs).

SonoVue must also not be used together with the medicine dobutamine (used for heart failure) in patients for whom dobutamine is not suitable. For the full list of restrictions, see the package leaflet.

Why is SonoVue approved?

SonoVue has been shown to be effective in improving ultrasound scans of the heart in adults and the bladder in children, and in measurements of blood flow. Side-effects were generally minor. The European Medicines Agency therefore decided that SonoVue's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of SonoVue?

The company will carry out a study to confirm the effectiveness of SonoVue in detecting vesicoureteral reflux in children and its impact on the way patients are managed.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of SonoVue have also been included in the summary of product characteristics and the package leaflet.

Other information about SonoVue

The European Commission granted a marketing authorisation valid throughout the European Union for SonoVue on 26 March 2001.

The full EPAR for SonoVue can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with SonoVue, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.