



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 June 2017  
EMA/CHMP/347620/2017  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### SonoVue

#### sulphur hexafluoride

On 22 June 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product SonoVue. The marketing authorisation holder for this medicinal product is Bracco International B.V.

The CHMP adopted a new indication associated with a new route of administration for intravesical use as follows:

#### "Ultrasonography of excretory urinary tract

SonoVue is indicated for use in ultrasonography of the excretory tract in paediatric patients from newborn to 18 years to detect vesicoureteral reflux. For the limitation in the interpretation of a negative urosonography, see section 4.4 and 5.1."

For information, the full indications for SonoVue will be as follows:<sup>2</sup>

#### *Intravenous use:*

"This medicinal product is for diagnostic use only.

SonoVue is for use with ultrasound imaging to enhance the echogenicity of the blood, or of fluids in the urinary tract which results in an improved signal to noise ratio.

SonoVue should only be used in patients where study without contrast enhancement is inconclusive.

#### Echocardiography

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

#### Doppler of macrovasculature

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in **bold**



SonoVue increases the accuracy in detection or exclusion of abnormalities in cerebral arteries and extracranial carotid or peripheral arteries in adult patients 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 in adult patients.

#### Doppler of microvasculature

SonoVue improves display of the vascularity of liver and breast lesions during Doppler sonography in adult patients leading to more specific lesion characterisation.

#### *Intravesical use*

#### **Ultrasonography of excretory urinary tract**

**SonoVue is indicated for use in ultrasonography of the excretory tract in paediatric patients from newborn to 18 years to detect vesicoureteral reflux. For the limitation in the interpretation of a negative urosonography, see section 4.4 and 5.1."**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.