

אפריל 2020

SonoVue®

Powder and Solvent for Dispersion for Injection

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר **סונוביו**.

בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלון.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

הרכב התכשיר:

Sulphur hexafluoride 8 µL/ml

התוויות מאושרות:

This medicinal product is for diagnostic use only.

SonoVue is for use with ultrasound imaging to enhance the echogenicity of the blood, 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 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 characterisation.

העלון לרופא עודכן באפריל 2020. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Use caution when treating anaphylaxis with epinephrine in patients on beta blockers since response may be poor or promote undesired alpha-adrenergic and vagotonic effects (hypertension, bradycardia).

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It should be emphasised that stress echocardiography not only can induce an ischaemic episode but also the stressors may induce predictable, dose-dependent effects on the cardiovascular system (e.g., increase in heart rate, blood pressure and ventricular ectopic activity for dobutamine, or decrease in blood pressure for adenosine and dipyridamole) as well as unpredictable, hypersensitivity reactions.

4.8 Undesirable effects

Adult population - Intravenous use

The safety of SonoVue after intravenous administration was evaluated in 4653 adult patients who participated in 58 clinical trials. The undesirable effects reported with SonoVue after intravenous administration were, in general, non-serious, transient and resolved spontaneously without residual effects. In clinical trials, the most commonly reported adverse reactions after intravenous administration are: headache, injection site reaction, and nausea.

Gastrointestinal disorders:

Not known: Vomiting

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In very rare cases, fatal outcomes have been reported in temporal association with the use of SonoVue. In all these patients there was a high underlying risk for major cardiac complications, which could have led to the fatal outcome.