נובמבר 2021

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

<u>הרכב התכשיר:</u>

Sulphur hexafluoride 8 µL/ml

<u>התוויות מאושרות:</u>

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 בנובמבר 2021. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

4.4 Special warnings and precautions for use

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Hypersensitivity reactions

Serious hypersensitivity reactions have been observed during or shortly following SonoVue administration in patients with no prior exposure to sulphur hexafluoride microbubbles products, including patients with prior hypersensitivity reaction(s) to macrogol, also known as polyethylene glycol (PEG).

SonoVue contains PEG. There may be increased risk of serious reactions in patients with prior hypersensitivity reaction(s) to PEG .

It is recommended to keep all patients under close medical supervision during and for at least 30 minutes following the administration of SonoVue to monitor the risk of serious hypersensitivity reactions.

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