הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 03.11.2015

שם תכשיר באנגלית ומספר הרישום SONOVUE (153-03-34004-00)

שם בעל הרישום Dexcel Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
		Indications
4. CLINICAL PARTICULARS **4.3 Contraindications** Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1. SonoVue is contraindicated in patients known or suspected right-to-left, bi-directional or transient right-to-left shunts, severe pulmonary hypertension (pulmonary artery pressure >90 mmHg), uncontrolled systemic hypertension, and in patients with adult respiratory distress syndrome. SonoVue should not be used in combination with dobutamine in patients with conditions suggesting cardiovascular instability where dobutamine is contraindicated. ~~The safety and efficacy of SonoVue have not been established in pregnant and lactating women therefore, SonoVue should not be administered during pregnancy and lactation (see Section 4.6).~~	**4. CLINICAL PARTICULARS** **4.3 Contraindications** Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1. SonoVue is contraindicated in patients known or suspected right-to-left, bi-directional or transient right-to-left shunts, severe pulmonary hypertension (pulmonary artery pressure >90 mmHg), uncontrolled systemic hypertension, and in patients with adult respiratory distress syndrome. SonoVue should not be used in combination with dobutamine in patients with conditions suggesting cardiovascular instability where dobutamine is contraindicated. The safety and efficacy of SonoVue have not been established in pregnant and lactating women therefore, SonoVue should not be administered during pregnancy and lactation (see Section 4.6).	**Contraindications**
		Posology, dosage& administration
		Special Warning and Special Precautions for use
		Interaction with Other

		Medicaments and other Forms of Interaction
4.6 Pregnancy and lactation Pregnancy No clinical data on exposed pregnancies are available. Reproduction studies have been performed in animals at doses up to at least 8 and 17 times the human dose based on body surface area (in rats and rabbits, respectively). Animal studies do not indicate impaired fertility or harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3 Preclinical safety data). Because animal reproduction studies are not always predictive of human response, SonoVue should be used during pregnancy only if clearly needed. ~~Caution should be exercised when prescribing to pregnant women.~~ As a precautionary measure, it is preferable to avoid the use of SonoVue during pregnancy. Breastfeeding It is not known if sulphur hexafluoride is excreted in human milk. However, based on its rapid elimination from the body via the expired air, it is considered that the breastfeeding can be resumed two to three hours after administration of SonoVue. Advise breast-feeding women to pump and discard breast milk once after the drug's administration. Because many drugs are excreted in human milk, caution should be exercised when SonoVue is administered to breast-feeding women.	**4.6 Pregnancy and lactation** Pregnancy No clinical data on exposed pregnancies are available. Reproduction studies have been performed in animals at doses up to at least 8 and 17 times the human dose based on body surface area (in rats and rabbits, respectively). Animal studies do not indicate impaired fertility or harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3 Preclinical safety data). Because animal reproduction studies are not always predictive of human response, SonoVue should be used during pregnancy only if clearly needed. Caution should be exercised when prescribing to pregnant women. Breastfeeding It is not known if sulphur hexafluoride is excreted in human milk**.** Based on the rapid clearance of SonoVue, advise breast-feeding women to pump and discard breast milk once after the drug's administration. Because many drugs are excreted in human milk, caution should be exercised when SonoVue is administered to breast-feeding women.	**Pregnancy and Fertility, Lactation**
Undesirable effects 4.8 The safety of SonoVue was evaluated in 4653 adult patients who participated in 58 clinical trials. The adverse reactions are classified by System Organ Class and frequency, using the following convention: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000), not known (cannot be estimated from the available data)	**4.8 Undesirable effects** The safety of SonoVue was evaluated in 4653 adult patients who participated in 58 clinical trials. The adverse reactions are classified by System Organ Class and frequency, using the following convention: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000), not known (cannot be estimated from the available data)	**Adverse events**

System Organ Class	Adverse Drug Reactions Frequency Category		
	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1000)	Not known Cannot be estimated from available data
Immune system disorders		Hypersensitivity*	~~Hypersensitivity, anaphylactic reaction, anaphylactoid reaction~~
Psychiatric disorders		Insomnia	
Nervous system disorders	Headache, paraesthesia, dizziness, dysgeusia	Sinus headache	~~Loss of consciousness,~~ Vasovagal reaction
Eye disorders		Vision blurred	
~~Cardiac and~~ Vascular disorders	Flushing	Hypotension	Arrhythmias, hypertensive episodes
Cardiac disorders			Myocardial infarction** Myocardial ischemia**
Respiratory, thoracic and mediastinal disorders	Pharyngitis		
Gastrointestinal disorders	Nausea, Abdominal pain	~~Abdominal pain~~	
Skin and subcutaneous tissue disorders	Pruritus, rash		
Musculoskeletal, connective tissue and bone disorders	Back pain		
General disorders and administration site conditions	Chest ~~pain, chest~~ discomfort~~, pain, fatigue~~, injection site reaction (including pain, warmth), feeling hot	Chest pain, pain, fatigue	
Investigations	Blood glucose increased		

~~In some of the cases of hypersensitivity, in patients with underlying coronary artery disease, myocardial ischemia and/or myocardial infarctions were also reported.~~

~~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.~~

* Cases suggestive of hypersensitivity may include: skin erythema, bradycardia, hypotension, dyspnoea, loss of consciousness, cardiac/cardio-respiratory arrest, anaphylactic reaction, anaphylactoid reaction or anaphylactic shock.

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