Experience Real Time Diagnosis with Contrast Echocardiography

SonoVue improves:
- the endocardial border delineation and the assessment of cardiac volumes\(^1\)
- the assessment of cardiac wall motion during rest and stress echocardiography\(^2\)
- the reproducibility of assessment of left ventricular function\(^1,3\)

2) Usefulness of ultrasound contrast for image enhancement during stress echocardiography, Ten Cate V., Echocardiography 2002, 19, 621-625
Sulphur Hexafluoride

Summary of product characteristics

For prescribing information please refer to the approved SPC in your country.

1. NAME OF THE MEDICINAL PRODUCT

SonoVue® 8/μm 0.5 ml powder and solvent for dispersion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains: 8/μm spherical gas vesicles. On reconstitution, 1 ml of the resulting dispersion contains 8 μl sulphur hexafluoride in the microbubbles, equivalent to 45 micrograms.

For a full list of excipients, see section 6.1.

3. PHARMACOLOGICAL FORM

SonoVue® is a kit including: 1 vial containing 25 mg of lyophilised powder, 1 pre-filled syringe containing 5 ml sodium chloride, 1 Mini-Spike transfer system. Information on the appearance of the reconstituted solution is given in section 6.6.

4.4 Special warnings and precautions for use

There is no apparent relationship with respect to occurrence of adverse events in the clinical studies for patients receiving various categories of the most common concomitant medications.

No clinical data on exposed pregnancies are available. Animal studies do not indicate harmful effects with respect to reproduction, embryonal development, parturition or postnatal development (see section 5.3 Preclinical safety data). Caution should be exercised when prescribing to pregnant women. It is not known if sulphur hexafluoride is excreted in human milk. Therefore, caution should be exercised when SonoVue is administered to breast-feeding women.

4.7 Effects on ability to drive and use machines

On the basis of the pharmacokinetic and pharmacodynamic profiles, no or negligible influence is expected with the use of SonoVue on the ability to drive or use machines.

4.8 Undesirable effects

The undesirable effects reported with SonoVue were, in general, non-serious, transient and resolved spontaneously without residual effects. In clinical trials, the most commonly reported adverse reactions were headache (2.9%), injection site reaction including bruising, burning and paraesthesia at the injection site (1.7%) and injection site pain (1.4%).

4.9 Special precautions for storage

For storage conditions refer to the reconstituted medicinal product, see section 6.3. This medicinal product should be used immediately. If not used immediately, it should be stored frozen (2 to 8°C).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The pharmacodynamic effects of SonoVue is the creation of a gas-contrast microbubble dispersion within the circulation, producing both echogenicity and improved Doppler signal to noise ratio.

5.2 Pharmacokinetic properties

The presence of SonoVue® in the circulation is minimal, lasting for less than 10 minutes.

6. ADVERSE REACTIONS

6.1 List of excipients

Powder: Macrogol 4000, Dibasic potassium hydrogen phosphate, Sodium chloride. Solution: Sodium chloride 9 mg/ml (0.9%) solution for injection.

6.2 Incompatibilities

Dipalmitoylphosphatidylglycerol Sodium, Palmitic acid. Solvent: Sodium chloride 9 mg/ml (0.9%) solution for injection.

6.3 Shelf life

This medicinal product should be used immediately. If not used immediately, it should be stored frozen (2 to 8°C).

6.4 Special precautions for storage

For storage conditions refer to the reconstituted medicinal product, see section 6.3. This medicinal product should be used immediately. If not used immediately, it should be stored frozen (2 to 8°C). If the product is not used immediately, it should be stored in the refrigerator (2 to 8°C).

6.5 Stability

For the use of Registered Medical Practitioner, Hospital or Laboratory only.

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