PRESCRIBING INFORMATION

OPTISON™ 0.19 mg/ml dispersion for injection (Human albumin microspheres containing perflutren)

Please refer to full Summary of Product Characteristics before prescribing.

PRESENTATION
Dispersion for injection supplied as 1 vial of 3 ml and 5 vials of 3 ml. OPTISON consists of perflutren-containing microspheres of heat treated human albumin, suspended in human albumin solution, 1%.

CONCENTRATION
Perflutren-containing microspheres, 5·8 ± 10³/ml with a mean diameter of approximately 1.5-4.0 µm. Each ml of OPTISON is 0.19 mg. INDICATIONS This medicinal product is for diagnostic use only. OPTISON is a transpulmonary echocardiographic contrast agent for use in patients with suspected or established cardiovascular disease to provide left ventricular opacification after intravenous administration. It is intended for left ventricular opacification after intravenous administration.

Ultrasound imaging must be performed during injection of OPTISON as optimal contrast effect is obtained immediately after administration. The recommended dose is 0.5-3.0 ml per patient. A dose of 3.0 ml is usually sufficient, but some patients may require higher doses. The total dose should not exceed 8.7 ml per patient. The duration of the useful imaging time is 2.5-4.5 minutes for a dose of 0.5-5.0 ml. OPTISON is not the maximum record, tended clinical dosage limit.

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients. Pulmonary hypertension with a systolic pulmonary artery pressure >90 mm Hg.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE
Hypersensitivity has been reported. Care should therefore be exercised. A course of action should be planned in advance with necessary drugs and equipment available for immediate treatment, in case a serious reaction should occur. The experience of OPTISON in severely ill patients is limited. There is limited clinical experience with OPTISON in patients with certain severe states of cardiovascular or pulmonary disease or in patients with known allergy to plasma proteins. OPTISON should not be used in these categories of patients only after careful consideration, and monitored closely during and after administration. Other routes of administration not specified in section “Dosage and method of administration” above (e.g. intracoronary injection) are not recommended. Standard measures to prevent severe heart failure (NYHA IV), endocarditis, acute myocardial infarction with angina or uncontrolled hypertension, acute respiratory distress syndrome, septic shock, severe gastrointestinal bleeding, shock, severe liver failure, severe sepsis, known states of hypercoagulation or thrombembolism, renal or hepatic end-stage disease. OPTISON should be used with caution in patients with acute pulmonary oedema and in patients with severe renal impairment (creatinine clearance <30 ml per minute).

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS

The administration of human albumin has been shown to be safe in patients with suspected or established cardiovascular disease who are undergoing cardiac catheterization or angiography. EXAMINATION OF THE CHAMBERS Echocardiography should be accompanied by ECG monitoring. In animal studies, ultrasound imaging must be performed during injection of OPTISON as optimal contrast effect is obtained immediately after administration. Dosage: The recommended dose is 0.5-3.0 ml per patient. A dose of 3.0 ml is usually sufficient, but some patients may require higher doses. The total dose should not exceed 8.7 ml per patient. The duration of the useful imaging time is 2.5-4.5 minutes for a dose of 0.5-5.0 ml. OPTISON is not the maximum record, tended clinical dosage limit.

OVERDOSE
No case of overdose has been reported. In the phase I trial, healthy volunteers have received up to 44.0 ml of OPTISON and experienced no significant adverse effects.

INSTRUCTIONS FOR USE AND HANDLING
Like all parenteral products, the vials of OPTISON should be inspected visually for integrity of the container. Vials are intended for single use only. Homogenous white suspension after resuspension. The rubber stopper must be removed before use. Do not perform air injection and do not inject air into the vial as this will damage the product.

The injection must be given in a large antecubital vein, preferably the right arm. Attach a three-way stopcock to the cannula. • The OPTISON vial must be inactivated and gently rotated for approximately three minutes to completely resuspend the microspheres. • Complete resuspension is indicated by a uniformly opaque white suspension and absence of any material on stopper and vial surfaces. • OPTISON should be withdrawn with care into a syringe within 1 minute after resuspension. • Any pressure instability within the vial should be avoided since it may cause disruption of the microspheres and loss of available contrast effect. • After injection any sterile needle should be stored or with a sterile 18 G needle before withdrawing the injection into the syringe. Do not inject air into the vial as this will damage the product. • Use the syringe immediately after the vial has been opened. Unsturbed syringe and must be resuspended before use. • Resuspend the microspheres in the syringe immediately before injection by holding the syringe horizontally between the palms of the hands and rolling it quickly back and forth for no less than 10 seconds. • Inject the suspension through the plastic cannula, no smaller than 20 G at a maximum injection rate of 1.0 ml/s. Waiting: Never use any other type of route but the open flow connection.

For injectable otherwise METABOLISM AND EXCRETION
Efficacy and safety in patients below 18 years has not been studied.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE
The use of OPTISON in Phase III human clinical studies have been mild to moderate with subsequent full recovery. In clinical trials with OPTISON, undesirable effects were reported as adverse events with the following frequencies: Very common: dizziness; common: rectal pain, nausea. Rare: Dizziness, paraesthesia, tinnitus, ventricular tachycardia. Not Known: Visual disturbances, allergic type symptoms (e.g. anaphylactoid reaction or -shock, facial oedema, urticaria).

SAFETY INFORMATION
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