

Sulphur Hexofluoride (Sonovue) microbubbles and sentinel node mapping

Information for patients



This leaflet contains information about sulphur hexafluoride (Sonovue), a contrast agent. Contrast agents help to make the internal body structures more visible during imaging tests.

It tells you:

- How the medicine works
- How it will be used
- Whether there are any side effects

Why have I been given this leaflet

This leaflet will help explain about the test and contrast agent so you can decide if you would like to go ahead with the procedure.

Breast cancer commonly spreads along tiny tubes called lymphatics to the lymph nodes in the armpit. The first lymph node the breast cancer spreads to is called the sentinel node. The current standard treatment for invasive breast cancers is to have the sentinel node removed in a small operation. This requires a general anaesthetic, will leave a small scar in the armpit and can be associated with occasional side effects (swelling of the arm, numbness in the inside of the upper arm and stiffness of the shoulder).

The sentinel node is identified by using a combination of two injections into the breast before surgery. One is a blue dye and the other contains a small quantity of a radioactive substance. These two injections work together to show the surgeon the sentinel node so that it can be removed. The node is then examined in the laboratory to see if it contains any cancer

cells. If cancer cells are found then often a second operation on the armpit is needed to remove all the glands.

Sulphur hexafluoride (Sonovue) microbubbles are now also being used to identify the sentinel node. The microbubbles can show on an ultrasound scan where the sentinel node is in the armpit and this allows a small sample to be taken under local anaesthetic, without the need for surgery. The sample is then looked at in the laboratory to see if any cancer cells are present.

Currently in 6 out of 10 women, the sentinel node removed from the armpit by surgery with the present standard treatment is free of cancer. If the microbubbles test was used in every patient, and if the test reliably found in every patient where there was no cancer spread to the sentinel lymph node, then the surgery to remove the sentinel node, and the associated side effects could be avoided in 6 out of 10 women. At the moment however, in 1-2 women out of 10, the microbubbles scan is inconclusive, and so currently we cannot rely on this test alone.

Therefore all women are having both the microbubble ultrasound scan and the standard sentinel node procedure with surgery to detect if breast cancer has spread to the armpit. Over time, doctors aim to reduce the number of inconclusive microbubble scans to zero, so that they are able to accurately find and sample the sentinel node in all patients without the need for surgery. We will be reviewing/auditing our results.

As this medicine is a diagnostic agent, there is no patient information in the medicine package. This medicine does not have a licence for being injected into the skin at the dose being used (subcutaneous injection of 0.2 - 0.5mls). We have written this leaflet to give you some extra information.

So this medicine does not have a licence. What does this mean?

The leaflet - Unlicensed Medicines, Information for patients tells you more about medicine licensing regulations. It also tells you why unlicensed medicines are sometimes used.

Why does sulphur hexafluoride (Sonovue) not have a licence?

Sometimes a medicine has been licensed for a certain use and later use shows that it works for a different illness or when given a different way. The manufacturer can then choose whether they apply to the government to have the more recent information added to the licence. This costs a lot of money so sometimes the manufacturer decides it is not worth their while.

Sulphur hexafluoride (Sonovue) is made by the manufacturer for injection into the veins for use as a contrast agent to take pictures of:

- the heart (echocardiography)
- large blood vessels such as those in the head or liver and smaller vessels such as those in the breast or liver

However it is also useful in identifying the lymphatic channels and nodes in the armpit and identifying the sentinel node in patients with breast cancer.

Remember that your doctor will have thought carefully about which medicine is best for your condition.

What is sulphur hexafluoride (Sonovue) and how does it work?

Sulphur hexafluoride (Sonovue) is a contrast agent. Contrast agents help to make the internal body structures more visible during imaging tests.

Sulphur hexafluoride (Sonovue) is a gas that does not dissolve in the blood or lymph fluid. The gas is made up into a suspension in liquid with the gas trapped into tiny bubbles called microbubbles. This is then injected into the tissue just under the skin near the nipple. Local anaesthetic makes the area numb.

If the sentinel lymph node is then visible on the ultrasound in the armpit region, a further small injection of local anaesthetic is given and the sentinel node is sampled.

When should sulphur hexafluoride (Sonovue) not be used?

Please tell your doctor or radiographer if you are allergic to sulphur hexafluoride (Sonovue) or any other ingredients in the injection. Please check with the radiographer or doctor.

This medicine should not be used if:

- you have uncontrolled high blood pressure, severe heart rhythm disorders or cardiac failure.
- you have had a recent heart attack or a surgical procedure on your heart or its blood vessels, chest pain at rest (angina) in the last seven days, worsening symptoms of heart failure (breathlessness, ankle or leg swelling), worsening heart rhythm test (ECG) results.

- you have an abnormal movement of blood within the heart (right to left shunt), high blood pressure in the blood vessel going from the heart to the lungs (pulmonary artery hypertension >90mmHg) or respiratory distress syndrome (severe fluid built up in both lungs).
- you may be pregnant or are breast feeding.
- you are under the age of 18.

Please tell your doctor or radiographer if any of these apply to you.

Extra care should be taken if you have heart disease, prosthetic valves, an infection affecting your whole body (systemic infection), hyperactive coagulation states or a recent thromboembolism (blood clot), lung disease such as chronic obstructive pulmonary disease (COPD) or severe kidney or heart disease.

Please tell your doctor or radiographer if any of these apply to you.

Are there any side effects?

Most medicines cause side effects. Sulphur hexafluoride (Sonovue) can sometimes cause:

- Headaches
- Flushing
- Tingling, burning, pricking or numbness of the skin
- Distortion of sense of taste (dysgeusia)
- Sore throat (pharyngitis)
- Sickness (nausea)
- Itchy skin (pruritis) or a rash
- Back or chest pain
- Tiredness (fatigue)
- Reactions at the injection site
- Feeling hot
- Raised blood sugar levels

Only contact your doctor if they carry on for more than a few days or make you feel worse.

Most rarely sulphur hexafluoride (Sonovue) can cause a sinus headache, blurred vision, stomach pain or insomnia. If you have any of these effects contact your doctor as soon as possible.

Everyone reacts differently to medicines, you may have some side effects or none at all.

Will sulphur hexafluoride (Sonovue) affect any other medicines?

Sulphur hexafluoride (Sonovue) is not known to affect any other medicines.

Can I drink alcohol the days before or after I have this injection?

Yes, it is safe to drink alcohol, however large quantities of alcohol should be avoided.

How can I find out more?

Your agreement should be obtained before prescribing any medicine. This leaflet has explained that sonovue microbubbles do not have a licence for use in sentinel node mapping and provided information about possible side effects. Please ask questions if you need more information.

You will be asked to say whether or not you want to take this medicine. If you agree, but later decide that you don't want sonovue microbubbles after all, that is fine. Please tell your doctor or radiographer.

This leaflet has been written to provide you with general information on sulphur hexafluoride (Sonovue). If you have any further questions or concerns, please speak to your doctor, pharmacist or radiographer.