

DEFINITY®

Perflutren

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Definity. It does not contain all of the available information about Definity. It does not replace talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving Definity against the benefits he or she expects it will have.

If you have any concerns about having this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What is Definity

Definity contains the active ingredient perflutren. Perflutren is a gas. Definity consists of perflutren-containing lipid microspheres dispersed in a solution that is given intravenously by infusion (drip) or injection.

Perflutren containing lipid microspheres enhance the images seen with ultrasound and give your doctor a clearer picture of your liver, kidneys or heart.

Your doctor may have prescribed Definity for another purpose. Ask your doctor if you have any questions about why Definity has been prescribed for you. If you have any concerns, you should discuss these with your doctor.

This medicine is for diagnostic use and is only available with a doctor's prescription.

Before you are given Definity

Before you are given Definity your doctor will explain to you the procedure you are about to undergo. You must discuss any concerns you have with your doctor.

When you must not be given Definity

You must not be given Definity if you have an allergy to:

- Perflutren or
- any of the other ingredients listed at the end of this leaflet.

You must not be given Definity if you have a cardiac shunt.

Before you are given Definity

You must tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

Symptoms of an allergic reaction include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or any other parts of the body

Tell your doctor if you are or plan to become pregnant.

Like most medicines Definity is not recommended for use during pregnancy. If there is a need to consider Definity during your pregnancy, your doctor will discuss the benefits and risks of giving it to you.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Like most medicines Definity is not recommended while you are breastfeeding. However if you are breastfeeding, formula feedings should be substituted for breastfeeding for 24 hours following the administration of Definity. Breast milk produced within that time should be discarded.

Tell your doctor if you have any other medical conditions,

especially if you have been told you have a heart shunt or have any mechanical device to aid your breathing.

Taking other medicines

Tell your doctor if you are taking any other medicines,

including medicines that you buy without a prescription from pharmacy, supermarket or health food shop.

How Definity is given

Definity is given to you before or during your ultrasound examination.

How much is given

Your doctor will decide how much you will be given. This depends on which organ (liver, kidney or heart) is being examined and other factors such as weight.

How it is given

Definity is given as an injection or infusion (drip) into a vein. You may be given more than one injection of Definity, followed by an injection of sodium chloride solution. Definity will only be given to you by a doctor or a nurse.

When you are given Definity

Things to be careful of

Do not drive or operate machinery until you know how Definity affects you.

Definity may cause dizziness in some people. Make sure you know how you react to Definity before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.

Side effects

Tell your doctor if you do not feel well during the injection or after being given Definity.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Tell your doctor or nurse if you experience any of the following and they worry you:

- headache
- flushing
- dizziness
- altered taste
- back pain
- pain at the injection site

These are usually mild and resolve within 15 minutes.

Tell your doctor or nurse immediately if you notice any of the following:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- changes in your heart rate
- feeling faint
- nausea, vomiting
- rash, itching or hives (itchy swellings on the skin)
- allergic reaction - shortness of breath or difficulty breathing, slow heart rate, dizziness or light-headedness, feeling unusually tired or weak

These are serious side effects for which you may need medical treatment.

Do not be alarmed by this list of side effects.

You may not experience any of them.

Product description

What it looks like

Definity is supplied in vials. An injection is prepared by shaking the vial immediately before it is injected. It is a milky white liquid.

Ingredients

Active ingredient:

Perflutren - after activation each mL of Definity contains a maximum of 1.2×10^{10} perflutren containing microspheres.

Other ingredients:

- 1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylcholine (DPPC),
- 1,2-dipalmitoyl-*sn*-glycero-3-phosphatidic acid,
- monosodium salt (DPPA),
- N-(methoxypolyethylene glycerol 5000 carbamoyl)-1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylethanolamine,
- monosodium salt (MPEG5000 DPPE),
- Sodium phosphate monobasic monohydrate,
- sodium phosphate dibasic heptahydrate,
- sodium chloride,
- propylene glycol,
- glycerine and
- water for injections.

Sponsor

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Registration Number

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