

# DEFINITY<sup>®</sup> perflutren lipid microsphere injection vial

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using [medicine name]?

DEFINITY<sup>®</sup> contains the active ingredient perflutren. DEFINITY<sup>®</sup> is used in patients on contrast-enhanced diagnostic ultrasound imaging to improve characterisation of focal lesions of the liver and kidney. It is also used in patients with suboptimal echocardiograms to provide opacification of cardiac chambers, improvement of left ventricular endocardial border delineation and assessment of regional wall motion at both rest and stress.

For more information, see Section [1. Why am I using \[medicine name\]?](#) in the full CMI.

### 2. What should I know before I use DEFINITY<sup>®</sup>?

Do not use if you have ever had an allergic reaction to DEFINITY<sup>®</sup>, Polyethylene glycol or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions especially if you are diagnosed with Sickle Cell Disease, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use \[medicine name\]?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with DEFINITY<sup>®</sup> and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use DEFINITY<sup>®</sup>?

- Your doctor will decide how much you will be given DEFINITY<sup>®</sup>. This depends on which organ (liver, kidney or heart) is being examined and other factors such as weight.
- DEFINITY<sup>®</sup> is given as an injection or infusion (drip) into a vein.

More instructions can be found in Section [4. How do I use \[medicine name\]?](#) in the full CMI.

### 5. What should I know while using DEFINITY<sup>®</sup>?

Things you should do	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are <b>allergic or hypersensitive to perflutren, polyethylene glycol (PEG)</b> or any of the ingredients listed at the end of this leaflet.</li><li>Remind your doctor if you have been diagnosed with <b>Sickle Cell Disease</b>.</li><li>Tell your doctor if you experience any side effects, <b>especially acute pain episodes such as moderate to severe back pain</b>, during or after the DEFINITY<sup>®</sup> administration.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li><b>Not notifying your doctor that you are pregnant, intend to be pregnant, breast feeding, intend to breastfeed, taking other medications and current medical conditions.</b></li></ul>
Driving or using machines	<ul style="list-style-type: none"><li><b>Do not drive or operate machinery</b> until you know how DEFINITY<sup>®</sup> affects you.</li></ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects are headache, flushing, dizziness, altered taste, back pain, pain at the injection site.

Serious side effects could be 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, itchin, hives; allergic reaction/anaphylactic (shortness of breath or difficulty breathing, slow heart rate, dizziness or light-headedness, feeling unusually tired or weak);

moderate to severe back pain and vaso occlusive crisis for patients with Sickle Cell Disease. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# DEFINITY<sup>®</sup> perflutren lipid microsphere injection vial

Active ingredient(s): *perflutren*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Definity<sup>®</sup>. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Definity<sup>®</sup>.**

Where to find information in this leaflet:

1. [Why am I using \[medicine name\]?](#)
2. [What should I know before I use \[medicine name\]?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use \[medicine name\]?](#)
5. [What should I know while using \[medicine name\]?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using DEFINITY<sup>®</sup>?

**Definity<sup>®</sup> contains the active ingredient perflutren.**

**Definity<sup>®</sup>** is a prescription medicine which is only available to the Healthcare Practitioners for diagnostic use only. It is administered to you via intravenous injection.

**Definity<sup>®</sup> is indicated for use in patients:**

- In contrast-enhanced diagnostic ultrasound imaging to improve characterisation of focal lesions of the liver and kidney.
- With suboptimal echocardiograms to provide opacification of cardiac chambers, improvement of left ventricular endocardial border delineation and assessment of regional wall motion at both rest and stress.

## 2. What should I know before I use DEFINITY<sup>®</sup>?

### Warnings

**Do not use Definity<sup>®</sup> if:**

- You are allergic or hypersensitive to perflutren, polyethylene glycol (PEG) or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- **You have or suspected of having cardiac shunts.**
- **You are below 18 years old.**

### Check with your doctor if you:

- Have any other medical conditions, especially if you have been told that you have a heart shunt or have any mechanical device to aid your breathing and if you have been diagnosed with Sickle Cell Disease.
- Have allergies, anaphylactic or hypersensitive to perflutren, polyethylene glycol or other ingredients listed at the end of this leaflet. Symptoms of allergic reactions are:
  - ✓ 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
- Take any medicines for any other condition, including medicines that you buy without prescription from pharmacy, supermarket or health food shop.
- You have chronic pulmonary vascular disorders.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DEFINITY<sup>®</sup>.**

## 4. How do I use DEFINITY<sup>®</sup>?

### How much to take / use

- Your doctor will decide how much you will be given DEFINITY<sup>®</sup>. This depends on which organ (liver, kidney

or heart) is being examined and other factors such as weight.

- DEFINITY<sup>®</sup> 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 to take / use DEFINITY<sup>®</sup>

- DEFINITY<sup>®</sup> 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.

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

### If you take too much DEFINITY<sup>®</sup>

If you think that you have been injected with too much DEFINITY<sup>®</sup> or experience immediate side effects, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using DEFINITY<sup>®</sup>?

### Things you should do

**Tell your doctor if you have been diagnosed with Sickle Cell Disease and/or 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

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• headache</li><li>• flushing</li><li>• dizziness</li><li>• altered taste</li><li>• back pain</li><li>• pain at the injection site</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li><li>• changes in your heart rate</li><li>• feeling faint</li><li>• nausea, vomiting</li><li>• rash, itching or hives (itchy swellings on the skin)</li><li>• allergic reaction – shortness of breath or difficulty breathing, slow heart rate, dizziness or light-headedness, feeling unusually tired or weak</li><li>• acute pain episodes such as moderate to severe back pain and vaso occlusive crisis (VOC)</li></ul>	<b>Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is only with a doctor's prescription and only made available to your doctor only.

## What [medicine name] contains

<b>Active ingredient (main ingredient)</b>	Perflutren
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• (R) - hexadecanoic acid, 1 – [(phosphonoxy)methyl]-1,2-ethanediyl ester, monosodium salt (abbreviated DPPA)</li><li>• (R) - 4-hydroxy-N,N,N-trimethyl-10-oxo-7-[(1-oxohexadecyl)oxy]-3,4,9-trioxa-4-phosphapentacosan-1-aminium, 4-oxide, inner salt (abbreviated DPPC);</li><li>• (R) α-[6-hydroxy-6-oxido-9-[(1-oxohexadecyl)oxy]5,7,11-trioxa-2-aza-6-phosphahexacos-1-yl]-ω-methoxypoly(ox-1,2-ethanediyl), commonly called N-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-dipalmitoyl-sn-glycero-3-phosphatidylethanolamine, monosodium salt (abbreviated MPEG5000 DPPE)</li><li>• Propylene Glycol</li><li>• Glycerine</li><li>• Monobasic sodium phosphate monohydrate</li><li>• Dibasic sodium phosphate heptahydrate</li><li>• Sodium chloride</li><li>• Water for injection</li></ul>
<b>Potential allergens</b>	Polyethylene Glycol

**Do not take this medicine if you are allergic to any of these ingredients.**

## What DEFINITY® 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. (Aust R 124808).

## Who distributes [medicine name]

Global Medical Solutions Australia Pty Limited T/A  
Radpharm Scientific

53-57 Oatley Court, BELCONNEN, ACT 2617 Australia

This leaflet was prepared on **23/1/2024**.