

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

# LIPIODOL ULTRA FLUID

## 480 mg of iodine per ml

### Solution for injection

Iodised ethyl-esters of the fatty acids of poppy seed oil

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

**In this leaflet:**

1. What Lipiodol Ultra Fluid is and what it is used for
2. Before you are given Lipiodol Ultra Fluid
3. How to use Lipiodol Ultra Fluid
4. Possible side effects
5. How to store Lipiodol Ultra Fluid
6. Further information

### 1. WHAT LIPIODOL ULTRA FLUID IS AND WHAT IT IS USED FOR

Lipiodol Ultra Fluid is a diagnostic agent. It belongs to the group of contrast agents used for radiological examinations.

Lipiodol Ultra Fluid is used to enhance the contrast of the images obtained during radiological examinations. This contrast enhancement improves the visualisation and outline of certain body parts.

This medicine is for diagnostic use only.

### 2. BEFORE YOU ARE GIVEN LIPIODOL ULTRA FLUID

You should read the information in this section carefully. You and your doctor should take the information into consideration before you are given Lipiodol Ultra Fluid.

**You should NOT be given Lipiodol Ultra Fluid if:**

- you are allergic to iodised ethyl-esters of the fatty acids of poppy seed oil (the active substance),
- you have an overactive thyroid gland (which can cause increased appetite, weight loss or sweating),
- you have recently had severe injury or bleeding,
- you are pregnant or think you are pregnant and are due to undergo hysterosalpingography (examination of the uterus and fallopian tubes)
- you have inflammation in the pelvis affecting your womb, tubes or ovaries are due to undergo hysterosalpingography (examination of the uterus and fallopian tubes).
- you need a bronchography, a type of X-ray examination where dye is instilled into the lower lung. Lipiodol Ultra Fluid is not suitable for this X-ray examination.

**Take special care with Lipiodol Ultra Fluid**

Inform your doctor if the following applies to you:

- you have previously reacted to this contrast agent during an examination
- you have an history of hypersensitivity to iodine
- you have asthma
- you have a disease affecting your heart or your blood vessels
- you have a disease affecting your lungs
- you have thyroid disorders or a history of thyroid disease
- you are due to undergo a thyroid examination in the near future or treatment with radioactive iodine

In all these cases, your doctor will only give you Lipiodol Ultra Fluid if the benefits outweigh the risks. If you are given Lipiodol Ultra Fluid, your doctor will take the precautions necessary and the administration of Lipiodol Ultra Fluid will be carefully monitored.

If you are a child or an elderly patient, your doctor will take special care when using lipiodol Ultra Fluid.

### Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, please inform your doctor or pharmacist if:

- you are taking or have recently taken medicines for:
  - heart and blood pressure disorders such as beta-blockers (tablets for calming the heart and decreasing the blood pressure)
- you have recently received interleukin-2 (a drug used to treat cancer or to reinforce your immune system, i.e. your internal defence system).

### Taking Lipiodol Ultra Fluid with food and drink

There are no known interactions between Lipiodol Ultra Fluid and food or drinks.

Lipiodol Ultra Fluid is administered by injection. Therefore, there is no special recommendation regarding intake of food and drink. However, please check with your doctor if it is required or not to eat or drink before the examination.

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Inform your doctor if:

- you are pregnant or might be pregnant
- your period is late
- you are breast-feeding

The product should not be used during pregnancy unless the benefits outweigh the risks. Your doctor will decide if the examination with Lipiodol Ultra Fluid is necessary. Lipiodol Ultra Fluid must not be given to you if you are pregnant or think you are pregnant and are due to undergo hysterosalpingography (examination of the uterus and fallopian tubes).

You should stop breast-feeding if you are given Lipiodol Ultra Fluid.

### Driving and using machines

Lipiodol Ultra Fluid is unlikely to affect your ability to drive or use machines. If you feel unwell after the examination, you should not drive or use machines.

### 3. HOW YOU ARE GIVEN LIPIODOL ULTRA FLUID

Lipiodol Ultra Fluid will be administered to you by injection. During the examination, you will be under the supervision of a doctor.

A needle may be left in your vein; this will allow the doctor to inject you with appropriate emergency drugs if necessary. If you experience an allergic reaction, the administration of Lipiodol Ultra Fluid will be stopped.

The attending staff knows what precautions have to be taken for the examination. They are also aware of the possible complications that can occur.

### Dosage

Your doctor will determine the dose you will receive. The dose will depend on the particular requirement of the examination that you need and on your body weight.

### If too much Lipiodol Ultra Fluid has been administered to you

You will be given the injection in a medical setting by a trained person. Therefore, it is highly unlikely that you will be given an overdose. An overdose can make you feel ill or unwell. Therefore, you should report any symptom you may have to your doctor. Your doctor will take the appropriate measures if necessary.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Lipiodol Ultra Fluid can cause side effects, although not everybody gets them.

There is a small risk that you may have an allergic reaction to Lipiodol Ultra Fluid. Such reactions can be severe and exceptionally result in shock (very rare case of allergic reaction that could put your life in danger).

**Any of the symptoms below mentioned may be the first signs of a shock. Inform your doctor or health professional immediately if you feel any of them:**

- swelling of the face, mouth, lips, eyelids or throat which may cause you difficulties in swallowing or breathing
- hypotension (low blood pressure)
- breathing difficulties
- whistling breathing
- coughing
- itching
- runny nose

- sneezing
- throat irritation or tightening
- eye irritation
- skin redness
- urticaria (skin itching nettlerash)

Other possible side effects:

- nausea (feeling sick)
- vomiting
- fever
- pain
- underactive thyroid gland (which can cause tiredness or weight gain)
- overactive thyroid gland (which can cause increased appetite, weight loss or sweating)
- swelling of the various parts of the body (legs, arms, neck)
- embolism (blockage of blood vessels) in brain, lung, liver and retina. This can occur without clinical signs.
- Granuloma (roughly spherical mass formed in the body by accumulation of oily residue and cells)

Most side effects are dose-related and dosage should therefore be kept as low as possible.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

## 5. HOW TO STORE LIPIODOL ULTRA FLUID

Keep out of the reach and sight of children.

Do not use Lipiodol Ultra Fluid after the expiry date which is stated on the ampoule and on the carton, after the abbreviation "Exp". The expiry date refers to the last day of that month.

Do not store above 25°C

Keep the ampoule in the outer carton.

It is unlikely that you will be asked to dispose of any left over Lipiodol Ultra Fluid. If this happens, ask your doctor what you should do. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Lipiodol Ultra Fluid contains

The active substance is iodised ethyl-esters of the fatty acids of poppy seed oil. 1 ml of solution for injection contains 480 mg of iodine.

The other ingredients: Lipiodol Ultra Fluid does not contain any other ingredients than the iodised ethyl-esters of the fatty acids of poppy-seed oil.

### What Lipiodol Ultra Fluid looks like and contents of the pack

Lipiodol Ultra Fluid is a solution for injection.

The solution is a pale yellow, clear oily liquid.

The Lipiodol Ultra Fluid pack contains one ampoule with 10 ml of solution for injection.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

**Guerbet**

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Manufacturer:

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**This leaflet was last revised in 04/2011.**

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