

LIPIODOL[®] ULTRA FLUID

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.

1. Why am I given LIPIODOL ULTRA FLUID?

LIPIODOL ULTRA FLUID contains the active ingredient iodised oil. LIPIODOL ULTRA FLUID is a diagnostic agent used during radiological examinations, and during surgery.

For more information, see Section [1. Why am I given LIPIODOL ULTRA FLUID?](#) in the full CMI.

2. What should I know before I am given LIPIODOL ULTRA FLUID?

You must not be given LIPIODOL ULTRA FLUID if you are allergic to the active substance, iodised oil. You must not be given LIPIODOL ULTRA FLUID if you need to undergo a bronchography, recently had severe injuries or major bleeding, you are, or think, pregnant, have acute pelvic inflammation and are due to undergo hysterosalpingography, have or suspected to have cancer in the reproductive tract, you have hyperthyroidism, have iodine idiosyncrasy, or if you have a blood clot in a liver vein.

Talk to your doctor, radiographer, or nurse if you have any other medical conditions, 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 am given LIPIODOL ULTRA FLUID?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LIPIODOL ULTRA FLUID 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 am I given LIPIODOL ULTRA FLUID?

LIPIODOL ULTRA FLUID is injected by a doctor. Where and how LIPIODOL ULTRA FLUID will be injected depend on the reason for which you are receiving it.

More instructions can be found in Section [4. How am I given LIPIODOL ULTRA FLUID?](#) in the full CMI.

5. What should I know while receiving LIPIODOL ULTRA FLUID?

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| Things you should do | <p>Tell your doctor, radiographer, or nurse if you:</p> <ul style="list-style-type: none">• Have a history of hypersensitivity to iodine,• Are, or intend to become, pregnant; breastfeeding, or plan to breastfeed.• Have or had any of the following medical conditions: heart failure/malformation, respiratory failure, thyroid disorder/disease, disease affecting your liver or kidneys, dilated veins in the oesophagus, diabetes, problems with ducts carrying bile, or large thyroid/goitre.• Are due to undergo a thyroid examination or treatment with radioactive iodine. |
| Looking after your medicine | <ul style="list-style-type: none">• Your doctor will store LIPIODOL ULTRA FLUID as recommended by the manufacturer. But if you have to transport LIPIODOL ULTRA FLUID from the pharmacy to your doctor, store it in a safe place away from light, where the temperature stays below 25°C, and keep the ampoules in the carton. |

For more information, see Section [5. What should I know while receiving LIPIODOL ULTRA FLUID?](#) in the full CMI.

6. Are there any side effects?

Serious side effects can include allergic reactions, which may result in swelling of the face, eyelids, lips or throat and may cause difficulties in breathing or swallowing; other allergic signs include skin redness, rash, itching, low blood pressure, runny nose, and eye irritation. Common side effects can include high fever, nausea, vomiting, diarrhoea, weight loss/gain, accelerated/slower heart rate, anxiety, insomnia, constipation, tiredness, enlarged thyroid size, pain in the lower abdomen, light-headedness, difficult breathing, inflamed pancreas or gall bladder, stomach pain, liver damage, skin damage.

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.

LIPIODOL® ULTRA FLUID

Active ingredient(s): *iodised oil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LIPIODOL ULTRA FLUID. **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 LIPIODOL ULTRA FLUID.**

Where to find information in this leaflet:

- [1. Why am I given LIPIODOL ULTRA FLUID?](#)
- [2. What should I know before I'm given LIPIODOL ULTRA FLUID?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given LIPIODOL ULTRA FLUID?](#)
- [5. What should I know while receiving LIPIODOL ULTRA FLUID?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given LIPIODOL ULTRA FLUID?

LIPIODOL ULTRA FLUID contains the active ingredient iodised oil. LIPIODOL ULTRA FLUID is a diagnostic agent; it belongs to the class of iodinated contrast agents used for radiological examination. LIPIODOL ULTRA FLUID is used to enhance the contrast of the images obtained during these radiological examinations, which improves the visualisation and outline of certain body parts. When mixed with certain medicines to treat cancer, LIPIODOL ULTRA FLUID carries and delivers the cancer medicine into the area to be treated.

LIPIODOL ULTRA FLUID is used during radiological examinations and during surgery.

2. What should I know before I am given LIPIODOL ULTRA FLUID?

Warnings

You must not be given LIPIODOL ULTRA FLUID if you:

- are allergic to iodised oil, also known as ethyl ester of iodised fatty acids of poppy seed oil, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- need to undergo a bronchography, a type of X-ray examination where a dye is directly administered into the lower lungs.
- have, or recently had, severe injuries or major bleeding.
- are pregnant, or think you are pregnant.

- have acute pelvic inflammation, and are due to undergo hysterosalpingography, an examination of the uterus and fallopian tubes.
- have or suspect to have cancer in the reproductive tract.
- have iodine idiosyncrasy.
- have hyperthyroidism, i.e. an overactive thyroid gland.
- have a blood clot in a liver vein.

Check with your doctor if you:

- are allergic to any other medicines or any foods, dyes, or preservatives.
- have a history of hypersensitivity to iodine.
- have or have had any of the following medical conditions:
 - disease affecting your heart or blood vessels (heart failure, heart malformation).
 - disease affecting your lungs (respiratory failure).
 - thyroid disorder or history of thyroid disease.
 - you are due to undergo a thyroid examination or treatment with radioactive iodine.
 - disease affecting your liver, i.e. cirrhosis.
 - disease affecting your kidneys.
 - dilated veins in the oesophagus.
 - are diabetic.
 - have problems with ducts which carry bile.
 - have a large thyroid or goitre.
- take any medicines for any other condition.

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.

If you receive this medicine whilst pregnant, your newborn should be tested to ensure they are producing the correct amount of thyroid hormone.

3. What if I am taking other medicines?

Tell your doctor 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.

Some medicines may interfere with LIPIODOL ULTRA FLUID and affect how it works. These include:

- Medicines prescribed for heart and high blood pressure disorders, i.e. beta-blockers, diuretics.
- Interleukin-2, a medicine prescribed to treat cancer or strengthen your immune system.
- A medicine to treat diabetes (metformin).

- Medicines you know are toxic to the kidneys (certain types of antibiotics or antivirals).

Check with your doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LIPIODOL ULTRA FLUID.

4. How am I given LIPIODOL ULTRA FLUID?

How much is given

The dose will depend on the particular examination that you need. Your doctor will determine the dose that you will receive and will supervise the injection.

How LIPIODOL ULTRA FLUID is given

Before the examination, a healthcare professional will prepare and administer this medicine to you by injection. Where and how this medicine will be injected depends on the reason for which you are receiving it.

You will be monitored for any side effects for at least 30 minutes after the injection.

You may be given antibiotics to prevent any infections occurring from the procedure.

When opened, this medicine should be used once only and any residue discarded.

If you are given too much LIPIODOL ULTRA FLUID

As you will be administered the injection under the supervision of your doctor in a hospital, it is highly unlikely that you will be given too much.

However, if you think you, or your child, have been given too much LIPIODOL ULTRA FLUID, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor or medical staff, 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 receiving LIPIODOL ULTRA FLUID?

Things you should do

Follow carefully the directions given to you by your doctor and other medical staff.

Tell your doctor if you are going to have any laboratory tests.

Looking after your medicine

As this medicine is being given to you by your doctor, it is extremely unlikely that you will be expected to look after the medicine. However, in the case that you may have to

transport it from the pharmacy to your doctor, it is important to store it in a safe place, away from light, where the temperature stays below 25°C. Keep the ampoule in the carton.

LIPIODOL ULTRA FLUID must not be used if the packaging is torn or shows signs of tampering or after the expiry date printed on the label.

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"> Digestive disorders such as nausea, vomiting, diarrhoea Pains and pain in the pelvis (lower abdomen). Following hysterosalpingography, a transient fever with pain in the pelvic area is often noted as well as the possibility of salpingitis (inflammation of fallopian tubes) or pelvioperitonitis (inflammation of the abdominal cavity or the pelvic cavity) Light headedness Skin damage Swelling of various parts of the body (legs, arms) High fever during the hours following the examination. | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Allergic reactions signs including:</p> <ul style="list-style-type: none"> Skin redness Rash Itching Hypotension (low blood pressure) Runny nose Eye irritation Swelling of the face, eyelids, lips or throat, which may cause you difficulties in breathing or swallowing Whistling breathing Sensation of stuffy nose Sneezing Cough Sensation of throat tightening Urticaria | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Other side effects you may experience are:

- Signs of an overactive thyroid gland such as weight loss, accelerated heart rate, increased intestinal transit rate, anxiety, and insomnia.
- Signs of underactive thyroid gland such as weight gain, slower heart rate, constipation, and tiredness.
- Increase in the size of your thyroid gland.
- Blockages of certain blood vessels in lungs, brain, liver, and retina.
- Formation of a spherical mass (granuloma) due to the accumulation of oil residue in cells.
- Difficult breathing.
- Inflamed pancreas.
- Inflamed gall bladder.
- Liver damage
- Small amounts of LIPIODOL ULTRA FLUID may leak into the blood supply and end up in other parts of the body such as blood vessels or arteries.

LIPIODOL ULTRA FLUID is available in packs of one glass ampoule with 10 mL of solution for injection.

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Who distributes LIPIODOL ULTRA FLUID

Guerbet Australia Pty Ltd
166 Epping Road, Level 2
Lane Cove, NSW, 2066
Australia.

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Tell your doctor if you notice anything else that may be making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available at radiological examination clinics.

What LIPIODOL ULTRA FLUID contains

| | |
|-------------------------------------------------|-----------------------------------------------------------------------------------|
| Active ingredient (main ingredient) | ethyl esters of iodised fatty acids of poppy seed oil (iodine content: 480 mg/mL) |
| Other ingredients (inactive ingredients) | This medicine does not contain any other ingredient |

What LIPIODOL ULTRA FLUID looks like

LIPIODOL ULTRA FLUID is a clear, bright pale yellow liquid.