

LIPIODOL ULTRA FLUID

solution for injection

Iodised oil

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given an injection of LIPIODOL ULTRA FLUID.

It tells you some of the more important points you need to know about this product.

If you have any questions, want to know more about LIPIODOL ULTRA FLUID or are unsure about anything, ask your specialist or radiologist.

This leaflet provides only a summary of the information known about LIPIODOL ULTRA FLUID.

Remember that this injection is only for you. Only a doctor can prescribe it for you.

What is LIPIODOL ULTRA FLUID

LIPIODOL ULTRA FLUID is a diagnostic agent. It belongs to the class of iodinated contrast agents used for radiological examinations.

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 in radiological examinations of the uterus and Fallopian tubes when searching for causes of infertility.

What LIPIODOL ULTRA FLUID is used for

This medicine is used:

- during radiological examinations,
- during surgery.

Before receiving it

When you must not be given it

You must not be given LIPIODOL ULTRA FLUID:

- If you are allergic to the active substance, iodised oil, also known as ethyl ester of iodised fatty acids of poppy seed oil,
- If you need to undergo a bronchography, a type of X-ray examination where a dye is directly administered into the lower lungs,
- If you have or have recently had severe injuries or major bleeding,
- If you are pregnant or think you are pregnant; or have acute pelvic inflammation, and are due to undergo hysterosalpingography, an examination of the uterus and fallopian tubes,
- If you have or suspect to have cancer in the reproductive tract,
- If you have iodine idiosyncrasy,
- If you have hyperthyroidism, i.e. an overactive thyroid gland,
- If you have a blood clot in a liver vein.

This medicine must not be injected directly into your arteries or your veins.

Before you are given it

You must tell your doctor if:

- You are allergic to any other medicines or any foods, dyes or preservatives.
- You have a history of hypersensitivity to iodine,
- You are pregnant, intend to become pregnant or breastfeeding or plan 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.
- You have or have had any of the following medical conditions:
 - disease affecting your heart or your 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,
 - you are diabetic,
 - you have problems with ducts which carry bile,
 - you have a large thyroid or goitre.

Taking other medicines

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

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 to strengthen your immune system.
- A medicine to treat diabetes (metformin).
- Medicines you know are toxic to the kidney (i.e. certain antibiotics or antivirals).

How it is given

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 it 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 this medicine.

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 procedures.

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

If too much is given (overdose)

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 experience any side effects after being given LIPIODOL ULTRA FLUID Injection, tell your doctor or nurse immediately.

You may need urgent medical attention.

Also, immediately tell the doctor or medical staff or telephone the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice if you think a child or anyone else may have been given too much LIPIODOL ULTRA FLUID.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

After receiving it

Things you must do

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

Things to be careful of

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

Side effects

Like all medicines, LIPIODOL ULTRA FLUID can cause side effects, although not everybody gets them.

Tell your doctor immediately if any of these allergic signs occur:

- 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.

The other possible signs of an allergic reaction are:

- Whistling breathing,
- Sensation of stuffy nose,
- Sneezing,
- Cough,
- Sensation of throat tightening,
- Urticaria.

The allergic reaction can be exceptionally serious.

The other side effects you may experience are:

- High fever during the hours following the examination,
- Digestive disorders such as nausea, vomiting, diarrhoea,
- Signs of an overactive thyroid gland such as weight loss, accelerated heart rate and increased intestinal transit rate, anxiety and insomnia,

- Signs of an underactive thyroid gland such as weight gain, slower heart rate, constipation and tiredness,
- Increase in size of your thyroid gland
- Pains and pain in the pelvis (lower abdomen),
- Blockages of certain blood vessels in lung, brain, liver and retina,
- Formation of a spherical mass (granuloma) due to the accumulation of oil residue and cells,
- Light-headedness,
- Difficult breathing,
- Inflamed pancreas,
- Inflamed gall bladder,
- Stomach pain,
- Liver damage,
- Skin damage,
- Increase in thyroid gland volume,
- 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,
- Swelling of various parts of the body (legs, arms),
- 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).

Tell your doctor if you notice anything else that is 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 above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

As this 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.

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

Keep all medicines in a safe place where children cannot reach them.

They may be dangerous to children.

Product description

What it looks like

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

It is available in packs of one glass ampoule with 10 mL of solution for injection.

Ingredients

LIPIODOL ULTRA FLUID contains the active substance ethyl esters of iodised fatty acids of poppy seed oil (iodine content: 480

mg/mL). It does not contain any other ingredients.

The Australian Registration number is AUST R 34371.

Sponsor

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