

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 or are unsure about anything, ask your specialist or radiologist.

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

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

What is LIPIODOL

LIPIODOL ULTRA FLUID belongs to the class of iodinated contrast agents and contains the active substance ethyl esters of iodised fatty acids of poppy seed oil (iodine content: 48% i.e. 480 mg/mL). It does not contain any other ingredients.

It 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.

What LIPIODOL is used for

This medicine is used:

- during a radiological examination,
- during a surgical operation.

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 (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 lungs)
- if you have or have recently had severe injuries with major bleeding
- hysterosalpingography during pregnancy or acute pelvic inflammation
- Iodine idiosyncrasy
- if you suffer from documented hyperthyroidism.

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

Before you are given it

You must tell your doctor if:

1. You are allergic to any other medicines or any foods, dyes or preservatives.
2. You are pregnant, intend to become pregnant or breast-feeding or plan to breast-feed. If

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

3. You have or have had any of the following medical conditions:
 - heart or lung disease (heart or respiratory failure, heart malformation).
 - thyroid problem.
 - about to undergo a thyroid examination or treatment with radioactive iodine.

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 a heart disease or for high blood pressure (beta-blockers, diuretics),
- interleukin-2, a medicine prescribed to treat cancer or to strengthen your immune system.

How it is given

How much is given

The 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 product to you by injection. Where and how this medicine will be injected depends on the reason why you are taking this medicine.

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

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

If too much is given

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 Injection, tell your doctor or nurse immediately.

You may need urgent medical attention.

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 and/or 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,
- pain,
- 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.

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

Store below 25°C, protected from light.

Do not use LIPIODOL 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

LIPIODOL ULTRA FLUID is a clean, bright pale yellow sterile oil

in a 10 mL glass ampoule. Pack size of 1.

The Australian Registration number is AUST R 34371.

Sponsor

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This leaflet was revised in April 2018.