PRODUCT INFORMATION
LIPIODOL® ULTRA-FLUID
solution for injection

NAME OF THE MEDICINE
Lipiodol Ultra Fluid, 480 mg I/mL, solution for injection is an iodinated, non water-soluble contrast agent.

DESCRIPTION
Lipiodol Ultra Fluid is for diagnostic use only.
It is an opaque medium for use in certain radiological investigations, where it is desired to outline a viscus or other structure with directly instilled radio-opaque material. It is slowly absorbed from most sites in the body, but from the peritoneal cavity (after hysterosalpingography) absorption is relatively rapid.
Lipiodol Ultra Fluid is a clean, bright pale yellow, sterile oil in a glass ampoule. Each ampoule contains 10 mL of the active, ethyl esters of iodised fatty acids of poppy seed oil corresponding to an iodine content of 480 mg/mL. It does not contain any excipient.
Viscosity at 15°C: 70 cP (centipoises);
Viscosity at 37°C: 25 cP;
Relative density at 15°C: 1.280;
ATC code: V08AD01 (V:other)

INDICATIONS
Hysterosalpingography; lymphangiography; urethrography; radiography of the seminal vesicles, vas deferens and epididymis; nasal sinuses (for which purpose dilution to one-half or one-third strength with liquid paraffin or a suitable vegetable oil is generally advised); dacryocystography; sialography and the exploration of sinuses, fistulae, etc. It has also been used in the form of a 20% emulsion for the X-ray examination of empyema cavities.

CONTRAINDICATIONS
- Hypersensitivity to Lipiodol Ultra Fluid (ethyl esters of iodised fatty acids of poppy seed oil)
- Lipiodol Ultra Fluid is unsuitable for bronchography
- Recent haemorrhage in the region of investigation
- Hysterosalpingography during pregnancy or acute pelvic inflammation
- Iodine idiosyncrasy: It is strongly recommended that the patient be tested for iodine idiosyncrasy before the administraton of Lipiodol Ultra Fluid in other than small amounts. Simple and reliable tests can be effected by painting an area of the skin with iodine solution or by giving potassium iodine orally for a few days. Iodism occurs more frequently with Lipiodol Ultra Fluid than with organic salts of iodine.
- Documented hyperthyroidism
- Lipiodol Ultra Fluid must not be administered by intra-arterial or intravenous injection.

PRECAUTIONS
Hypersensitivity
There is a risk of hypersensitivity regardless of the dose administered.
All iodinated contrast agents can lead to minor or major hypersensitivity reactions, which can be life threatening. They can be immediate (occurring within 60 minutes) or delayed (not occurring until up to 7 days later). Anaphylactic reactions are immediate and can be fatal.
The risk of a major reaction means that the equipment needed for emergency resuscitation must be immediately at hand.
Patients who have already experienced a reaction after a previous administration of Lipiodol Ultra Fluid or who have a history of iodine hypersensitivity are at increased risk of another reaction on re-administration of the product (see CONTRAINDICATIONS).
The injection of this medicine may aggravate symptoms of a pre-existing asthma. In patients whose asthma is not controlled by treatment, the decision to administer Lipiodol Ultra Fluid requires careful prior review of the risk/benefit ratio.

Lymphography
Pulmonary embolism occurs in the majority of patients undergoing lymphography with Lipiodol Ultra Fluid injection since a fraction of the product temporarily embolises the pulmonary capillaries. Evidence of such embolization is infrequent, usually immediate however possibly delayed from a few hours to days and usually of a transient nature. For this reason, the doses should be adjusted or the examination cancelled in patients presenting with impaired respiratory function, cardiorespiratory insufficiency or pre-existing right cardiac overload, particularly if the patient is elderly. Patients should be warned about the possible signs of pulmonary embolism and to contact their doctor or hospital if any symptoms emerge.

Thyroid
Iodinated contrast media can affect thyroid function because of the free iodine content and can cause hyperthyroidism in predisposed patients. Patients at risk are those with latent hyperthyroidism and those presenting with functional thyroid autonomy. Iodism occurs more frequently with Lipiodol Ultra Fluid than with water soluble organic iodine derivatives.
Lymphography saturates the thyroid with iodine for several months and any thyroid function tests should therefore be conducted prior to the radiological examination.

Use in pregnancy
The safety of Lipiodol Ultra Fluid during pregnancy has not been demonstrated and therefore should only be used in pregnancy if absolutely necessary and under strict medical supervision.
It must not be used for hysterosalpingography when pregnancy is suspected or confirmed.

Miscellaneous
The injection of Lipiodol Ultra Fluid into certain fistulae should be conducted with great care in order to avoid penetration of vascular channels and the possibility of oil emboli. Care should be taken not to inject the product into an area affected by haemorrhage or trauma.
Lipiodol Ultra Fluid has been shown to dissolve polystyrene. Disposable syringes made from the latter must not be used. The product should be administered using a glass syringe.

INTERACTIONS WITH OTHER MEDICINES
Combinations to be taken into account
- Beta blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers.
  These medicines reduce the effectiveness of the cardiovascular mechanisms that compensate for blood-pressure disturbances.
- Interleukin II (IV)
  There is an increased risk of reaction to contrast media in the event of recent interleukin II administration (IV route): skin rash or more rarely hypotension, oliguria or even renal failure.

Interference with diagnostic tests
As Lipiodol Ultra Fluid remains in the body for several months, the results of thyroid diagnostic tests may be incorrect for up to 2 years after lymphography.

ADVERSE EFFECTS
Severe allergic reactions have occurred in patients with a hypersensitivity to iodine so adrenaline and oxygen should be available at the time of administration and the patient pre-tested for allergy. Other dangers include oil embolism and venous intravasation.

Post marketing adverse effects
The adverse effects are presented in the table below, by system organ class and by frequency using the following categories: very common (≥1/10), common (≥1/100 to 1<1/10), uncommon (≥1/1000 to 1<1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000), not known (cannot be estimated from the available data).

System organ class	Frequency: Adverse reaction
Immune system disorders	Unknown: hypersensitivity, anaphylactic reaction, anaphylactoid reaction
Endocrine disorders	Unknown: hypothyroidism, hyperthyroidism, thyroiditis
Nervous system disorders	Unknown: cerebral embolism
Eye disorders	Unknown: retinal vein thrombosis
Vascular disorders	Unknown: Lymphoedema aggravation
Respiratory, thoracic and mediastinal disorders	Unknown: pulmonary embolism, dyspnoea, cough
Gastrointestinal disorders	Unknown: vomiting, diarrhoea, nausea
Hepatobiliary disorders	Unknown: hepatic vein thrombosis
General disorders and administration site conditions	Unknown: granuloma, fever, pain

DOSAGE AND ADMINISTRATION
For administration via a suitable glass syringe and cannula by slow injection or cannulation.
After the administration of Lipiodol Ultra Fluid, the patient must be kept under observation for at least 30 minutes.

Hysterosalpingography
Care is needed to avoid the risk of venous intravasation. The injection must therefore not be made either during the first few days after a menstrual period or in the few days before a menstrual period is due. When the injection is made by means of a cannula, direct trauma to the uterine mucosa must be avoided. Excessive pressure should not be used in making the injection, which should be avoided entirely when the endometrium and the cervix have been recently subjected to surgical trauma.
On account of the disadvantages and potential dangers (very rare instances of oil emboli and iodism) associated with the use of Lipiodol Ultra Fluid in hysterosalpingography, etc, many radiologists prefer to use water soluble contrast agents.

Lymphangiography
The lymph vessels should first be rendered visible with a subcutaneous injection of Patent Blue V. Lipiodol Ultra Fluid is then injected by means of an automatic infusion machine at a rate of 1 mL every ten minutes. The usual dosage to visualize the lymphatic system of the leg in the adult patient is 8 mL; in the arm, 3 to 4 mL is usually adequate to show the axillary glands. For bilateral examinations a total of 15 mL usually gives adequate filling of inguinal, iliac and para-aortic glands. In children, dosage is reduced according to bodyweight using approximately 0.25 mL/kg.
The procedure is usually carried out under local analgesia. Exposures are made at the end of the infusion; further films are taken 24 and 48 hours later.
The lymph glands retain Lipiodol Ultra Fluid for several weeks or months and changes in their appearance may be followed by serial radiographs for example, after a course of chemo- or radiotherapy.

Elderly
The product should be administered with caution in patients over 65 years presenting with underlying pathologies of the cardiovascular, respiratory or neurological system. In elderly patients with cardiorespiratory failure, the dose should be adapted or the examination itself cancelled, since a portion of the product will temporarily embolize the pulmonary capillaries.

OVERDOSAGE
Overdose may lead to respiratory, cardiac or cerebral complications, which can potentially be fatal. Microemboliams may occur more frequently in the context of overdose.
Management of overdose consists in initiating symptomatic treatment and maintaining vital functions in the shortest possible timeframe.
Sites performing contrast medium examinations must be equipped with medicines and equipment for emergency aid.
Contact the Poisons Information Centre on 131126 for management of overdose.

PRESENTATION AND STORAGE CONDITIONS
Presentation
Lipiodol Ultra Fluid is a clean, bright pale yellow, sterile oil in a 10 mL Type I glass ampoule.
Pack size of 1.

Storage
Store below 25°C, protected from light. If the product becomes opaque or dark amber in colour (approximately the colour of a 1% solution of potassium dichromate), it should not be used.

NAME AND ADDRESS OF THE SPONSOR
Aspen Pharmacare Australia
34-36 Chandos St
St Leonards NSW 2065
Australia

POISON SCHEDULE OF THE MEDICINE
Unscheduled.

DATE OF MOST RECENT AMENDMENT
14 September 2012

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Guerbet