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1. WHAT LIPIO D O L U LTRA-FLU ID  IS AN D  W HAT IT IS U SED  FO R

What Lipiodol Ultra-Fluid is
Lipiodol Ultra-Fluid belongs to the class of iodinated contrast agents. Lipiodol Ultra-Fluid enhances the contrast of images obtained during these examinations, which improves the visualisation and delineation of the contours of certain parts of the body.

When it is used
This medicinal product is used:
• During radiological examinations.
• During surgery.
• To prevent disorders related to iodine deficiency when iodinated salt or supplemented drinking water cannot be used.

2. WHAT YO U  N EED  TO  K N O W  BEFO RE YO U  U SE LIPIO D O L U LTRA-FLU ID

Do not use Lipiodol Ultra-Fluid
• If you are allergic to the active substance (ethyl esters of iodized fatty acids of poppy seed oil).
• During radiological examinations, you must not receive an injection of this medicinal product.
• You have, or have had, an allergic disorder such as:
  - hives,
  - allergy to iodine,
  - red patches that itch (eczema),
  - asthma,
  - hay fever.
• You have heart or lung disease (heart or respiratory failure, cardiac malformation).
• You have kidney disease (renal failure).
• You are diabetic.
• You have high levels of blood cholesterol (hypercholesterolemia).
• You are scheduled for a thyroid examination or treatment with radioactive iodine.
• You have, or have had, certain disorders that may result in difficulties in breathing or swallowing. Other possible signs of an allergic reaction are: wheezing, plugged nose, sneezing, coughing, dry throat, hives.

If you are being treated for iodine deficiency:
• If you have, or have had, liver or kidney disease.
• If you are over 45 years of age.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible effects not listed in this leaflet.

3. H O W  TO  U SE LIPIO D O L U LTRA-FLU ID

Dose
The dose depends on the reason for which it is being used.
Your doctor will determine the dose to be injected.

Route and method of administration
A health professional will prepare and inject this product before carrying out the examination.
The route and method of injection depend on the reason for which the medicinal product is being administered.

Duration of treatment
This medicine is administered only once.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Lipiodol Ultra-Fluid may cause side effects, although not everybody gets them.

Allergic reactions may occur. They are indicated by the following signs:
• Flushing, simples, itching and/or sudden swelling of the face, eyelids, lips or throat that may result in difficulties in breathing or swallowing. Other possible signs of an allergic reaction are: wheezing, plugged nose, sneezing, coughing, dry throat, hives.
• In exceptional cases, the reaction may be serious. If any of these signs occur, you should immediately contact your doctor.

Other possible side effects are:
• High fever in the hours following the examination.
• Gastrointestinal disorders such as nausea, vomiting, diarrhoea.
• Signs of an overactive thyroid such as weight loss, faster heartbeat and intestinal transit, nervousness and paranoia.
• Pains.
• Blockage of certain blood vessels in the lungs or brain.
• If you get any side effects, talk to your doctor or pharmacist. This includes any possible effects not listed in this leaflet.

5. H O W  TO  S T O R E LIPIO D O L U LTRA-FLU ID

Keep this medicine out of the sight and reach of children.
Do not use Lipiodol Ultra-Fluid after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Store protected from light.
Do not throw away medicinal products via wastewater or with household waste.
Ask your pharmacist how to throw away medicinal products you no longer use. These measures will help protect the environment.

6. CON TEN TS O F TH E PAC K  AN D  OTH ER IN FO RM ATIO N

What Lipiodol Ultra-Fluid contains
The active substance is: ethyl esters of iodized fatty acids of poppyseed oil (iodine content: 49%, i.e. 480 mg/mL).
Lipiodol Ultra-Fluid does not contain any other ingredients than the active substance.
What Lipiodol Ultra-Fluid looks like and contents of the pack
This medicinal product is a solution for injection in 5 or 10 mL ampoules.

MA holder / Distributor / Manufacturer
Guerbet
BP 5748
95493 ROISSY CDG Cedex
France

This leaflet was last revised in January 2013.
Detailed information on this medicinal product is available on the ANSM website (France).

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY
Take special care with Lipiodol Ultra-Fluid
An early polymerization reaction may exceptionally occur between Lipiodol Ultra-Fluid and certain surgical glues, or even certain batches of glue. Before using new batches of Lipiodol Ultra-Fluid or surgical glue, the compatibility of Lipiodol Ultra-Fluid and the glue must be tested in vitro.

Method and route of administration
This product must be administered using a glass syringe.

In diagnostic radiology:
Lymphography: STRCT INTRALYMPHATIC USE
Diagnosis of lymph nodes
STRCT SELECTIVE INTRA-ARTERIAL USE
In interventional radiology:
Embolization with surgical glue
STRCT SELECTIVE INTRA-ARTERIAL USE
In surgery:
STRCT INTRAMUSCULAR USE

DRIVING AND USING MACHINES
Lipiodol Ultra-Fluid should not affect your ability to drive or use machines. However, if you do not feel well after taking this medicinal product, you should not drive or use machines.