SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

LIPIODOL ULTRA-FLUIDE (480 mg I/ml), solution for injection.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Ethyl esters of iodized fatty acids of poppy seed oil * qs ad for one ampoule

* Iodine content: 48 %, i.e. 480 mg per ml.

PHARMACEUTICAL FORM

Solution for injection.

CLINICAL PARTICULARS

Therapeutic indications

In diagnostic radiology

- Lymphography

- Hysterosalpingography (HSG) in women undergoing infertility workup

In interventional radiology

- Visualisation, localisation and vectorisation during Trans-Arterial Chemo-Embolisation (TACE) of hepatocellular carcinoma at intermediate stage, in adults.

Posology and method of administration

LIPIODOL ULTRA-FLUIDE must be administered by slow injection or by catheter using an appropriate a glass syringeand a catheter.

In diagnostic radiology

- Lymphography

The usual dose is 5 to 7 ml via the strict lymphatic route to enhance contrast in an extremity (depending on the height of the patient), i.e. 10 to 14 ml for bilateral lymphography of the feet.

- Hysterosalpingography

Inject increments of 2 mL of LIPIODOL ULTRA FLUIDE into the endometrial cavity under fluoroscopic control until tubal patency is determined.
The total volume to be injected depends on the volume of the uterine cavity, usually not exceeding 15 mL.
The dose of LIPIODOL ULTRA FLUIDE for hysterosalpingography should be kept as low as possible to minimize the potential risk of thyroid dysfunction.

Administration in hysterosalpingography is by slow injection into the uterine cervical canal via a suitable catheter or cannula. Stop the injection if the patient develops excessive discomfort. The examination should be preferably carried out during the follicular phase of the menstrual cycle.

In interventional radiology:
• Trans-Arterial Chemo-Embolisation of hepatocellular carcinoma:
The administration is by selective intra-arterial catheterism of the hepatic artery. The procedure should be performed within a typical interventional radiology setting with the appropriate equipment. The dose of LIPIODOL ULTRA-FLUIDE depends on the extent of the lesion, but should usually not exceed a total dose of 15 mL in adults.

LIPIODOL ULTRA-FLUIDE can be mixed with anticancer drugs such as cisplatin, doxorubicin, epirubicin and mitomycin. Instructions and precautions for use of the anticancer drugs must be strictly followed.

Instructions for preparation of the mixture of LIPIODOL ULTRA-FLUIDE with an anticancer drug:
- Prepare two syringes large enough to contain the total volume of mixture. The first syringe contains the anticancer drug solution, the second syringe contains LIPIODOL ULTRA-FLUIDE.
- Connect the two syringes to a 3-way stopcock.
- Perform 15 to 20 back and forth movements between the two syringes to obtain a homogeneous mixture. It is recommended to start by pushing the syringe with the anticancer drug first.
- The mixture is to be prepared at the time of use and must be used promptly after preparation (within 3 hours). If necessary during the interventional radiology procedure, the mixture can be re-homogenised as described above.
- When the adequate mixture is obtained, use a 1 to 3 mL syringe to inject in the micro-catheter.

The procedure can be repeated every 4 to 8 weeks according to tumour response and patient conditions.

Paediatric population
The efficacy and safety of the use of LIPIODOL ULTRA-FLUIDE for Trans-Arterial Chemo-Embolisation of hepatocellular carcinoma have not been established in children.

Elderly
The product must be administered with special care in patients over 65 years of age with underlying diseases of the cardiovascular, respiratory or nervous systems.

Contraindications

This product must not be administered by systemic intra-arterial, intravenous or intrathecal injection.

- Hypersensitivity to LIPIODOL ULTRA-FLUIDE (ethyl esters of iodised fatty acids of poppy seed oil)
- Confirmed hyperthyroidism

- Traumatic lesions, haemorrhage or recent bleeding (risk of extravasation or embolism)
- Bronchography (the product rapidly inundates the bronchioles and alveoli
- Hysterosalpingography during pregnancy, acute pelvic inflammation, marked cervical erosion, endocervicitis and intrauterine bleeding, within 30 days of curettage or conization.

Contraindications specific to the use in interventional radiology:
• Trans-Arterial Chemo-Embolisation
To prevent the occurrence of biloma, in the context of TACE procedure, LIPIODOL ULTRA-FLUIDE must not be administered in liver areas with dilated bile ducts unless drainage has been performed.

Special warnings and special precautions for use

LIPIODOL ULTRA-FLUIDE must not be administered intravenously, intra-arterially (apart from selective catheterisation) or intrathecally.
There is a risk of hypersensitivity whatever the dose administered.

Warnings

Hypersensitivity
All iodinated contrast agents may cause minor or major hypersensitivity reactions that may be life-threatening. These hypersensitivity reactions may be either allergic (described as anaphylactic reactions when serious) or non-allergic.
They may be immediate (within 60 minutes) or delayed (up to 7 days). Anaphylactic reactions occur immediately and can be fatal. They are independent of the dose, can occur after even the first dose of the product, and are often unpredictable.
Emergency resuscitation equipment must be immediately available due to the risk of major reaction. Patients who have previously experienced a reaction during administration of LIPIODOL ULTRA FLUIDE or who have a history of hypersensitivity to iodine are at higher risk of for another reaction if the product is again administered.
They are thus considered to be patients at risk. Injection of LIPIODOL ULTRA-FLUIDE may exacerbate of asthma. In patients whose asthma is not controlled by treatment, the decision to use LIPIODOL ULTRA-FLUIDE must be based on a careful consideration of the benefit to risk ratio.

Lymphography
Pulmonary embolism occurs in the majority of patients undergoing lymphography with injection of LIPIODOL ULTRA FLUID, as part of the product temporarily embolises the pulmonary capillaries. It is uncommon for this embolism to be manifested clinically; should this occur, the signs are immediate (though they may appear several hours or even several days after administration) and are usually transient. For this reason, doses must be adjusted or the examination cancelled in subjects with impaired respiratory function, cardiorespiratory failure or right ventricular overload, particularly if the patient is elderly. Doses must also be reduced after antineoplastic chemotheraphy or radiotheraphy because lymph nodes shrink significantly and retain very little contrast agent. The injection should be carried out with radiological or endoscopic guidance. Pulmonary invasion can be reduced to the minimum by confirming radiologically that the injection is strictly intralymphatic (and not intravenous) and by discontinuing the examination as soon as the contrast agent becomes visible in the thoracic duct or as soon as lymphatic obstruction is observed.

Thyroid
Because of the free iodine content in Iodinated contrast agents, they may modify thyroid function and cause hyperthyroidism in predisposed patients. Patients at risk are those with latent hyperthyroidism or thyroid autonomy. Iodism occurs more commonly with LIPIODOL ULTRA FLUIDE than with water soluble organic iodine derivatives.
Lymphography saturates the thyroid with iodine for several months and consequently thyroid function tests must be carried out before the radiological examination.

When used in hysterosalpingography in patients considered at risk for hypothyroidism, thyroid function should be monitored closely for several months after the examination to observe potential development of hypothyroidism. The dose of LIPIODOL ULTRA FLUIDE should be kept as low as possible to minimize the potential risk of thyroid dysfunction.

Hysterosalpingography
Intravasation of LIPIODOL ULTRA FLUIDE may occur in the course of a hysterosalpingography procedure and may result in serious pulmonary or cerebral embolic complications in the next hours following the procedure. The hysterosalpingography procedure should be immediately interrupted in case of suspected or confirmed intravasation of LIPIODOL ULTRA FLUIDE. The patient should be closely monitored for embolic complication in a care setting deemed appropriate by the treating clinician.

Embolic and thrombotic complications

The uncontrolled migration of LIPIODOL ULTRA-FLUIDE into the arterio-venous system may induce the temporary obliteration of small vessels (oil embolism) in various organs. Evidence of such embolisation is infrequent, usually immediate but can also be delayed occurring after a few hours or days and is usually transient. Most reported localizations of such an event include pulmonary embolisms, cerebral embolisms and skin embolisms (which could lead to skin necrosis). Patients should be warned of the possible signs of embolism and should contact their doctor or hospital if any symptoms emerge.

Trans-Arterial Chemo-Embolisation
Trans-Arterial Chemo-Embolisation is not recommended in patients with decompensated liver cirrhosis (Child-Pugh ≥8), advanced liver dysfunction, macroscopic invasion and/or extra-hepatic spread of the tumour.

Hepatic intra-arterial procedures can cause an irreversible liver insufficiency in patients with serious liver malfunction and/or undergoing close multiple sessions. More than 50% liver replacement with tumour, bilirubin level greater than 2 mg/dL, lactate dehydrogenase level greater than 425 mg/dL, aspartate aminotransferase level greater than 100 IU/L and decompensated cirrhosis have been described as associated with increased post-procedural mortality.

Oesophageal varices must be carefully monitored as they can rupture immediately after treatment. If a risk of rupture is demonstrated, endoscope sclerotherapy/ligature should be performed before the Trans-Arterial Chemo-Embolisation procedure.

Iodinated contrast agent induced renal insufficiency must be systematically prevented by correct rehydration before and after the procedure.

The risk of superinfection in the treated area is normally prevented by administration of antibiotics.

Precaution for use

Hypersensitivity

Before the examination:

identify patients at risk in a detailed interview on their history.

Corticosteroids and H1 antihistamines have been proposed as premedication in patients at greatest risk for hypersensitivity reactions (patients with known hypersensitivity to a contrast agent). However, they do not prevent the occurrence of serious or fatal anaphylactic shock.

Throughout the examination, maintain:

- medical monitoring
- an indwelling intravenous catheter.

After the examination:

After contrast agent administration, the patient must be monitored for at least 30 minutes, as most serious adverse reactions occur within this time period.

The patient must be warned of the possibility of delayed reactions (for up to seven days) (see Undesirable effects).

Thyroid

Possible thyroid risk factors must be investigated to prevent metabolic disorders. If iodinated contrast agents are to be administered to patients at risk, thyroid function tests must be carried out before the examination.

Trans-Arterial Chemo-Embolisation

Iodinated contrast agents can induce a transient deterioration of renal function or exacerbate pre-existing renal failure. The preventive measures are as follows:
• Identify patients at risk, i.e. patients who are dehydrated or who have renal failure, diabetes, severe heart failure, monoclonal gammopathy (multiple myeloma, Waldenstrom's macroglobulinemia), a history of renal failure after administration of iodinated contrast agents, children under one year of age and elderly atheromatous subjects.
• Hydrate the patient before and after the examination.
• Avoid combinations with nephrotoxic medicines. If such a combination is necessary, laboratory monitoring of renal function must be intensified. The medicines concerned are in particular the aminoglycosides, organoplatinums, high doses of methotrexate, pentamidine, foscarnet and certain antiviral agents [aciclovir, ganciclovir, valaciclovir, adefovir, cidofovir, tenofovir], vancomycin, amphotericin B, immunosuppressors such as cyclosporine or tacrolimus, ifosfamide)
• Allow at least 48 hours between radiological examinations or interventions with iodinated contrast agent injections, or delay further examinations or interventions until renal function returns to baseline.
• Check for lactic acidosis in diabetics treated with metformin, by monitoring serum creatinine. Normal renal function: discontinue metformin before and for at least 48 hours after

contrast agent administration or until renal function returns to baseline. Abnormal renal function: metformin is contraindicated. In emergencies, if the examination is required, precautions must be taken, i.e. discontinue metformin, hydrate the patient, monitor renal function and test for signs of lactic acidosis.
• Cardiovascular and/or pulmonary co-morbidities should be assessed before initiation of a Trans-Arterial Chemo-Embolisation procedure.

Miscellaneous
Injection into certain fistulas requires the utmost caution to avoid any vascular penetration, taking into account the risk of fat embolisms.

Care should be taken not to inject LIPIODOL ULTRA-FLUIDE into areas of bleeding or trauma.

Indications for the use of LIPIODOL ULTRA-FLUIDE must be carefully evaluated in patients with primary lymphoedema, as the condition may be exacerbated.

LIPIODOL ULTRA FLUIDE 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 or other administration system proven to be compatible with it.

Interactions with other medicinal products and other forms of interaction

Associations requiring precautions for use
• Beta-blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists
These medicinal products lead to a decrease in the effectiveness of the cardiovascular mechanisms that compensate for blood-pressure disturbances: the doctor must be informed before the administration of LIPIODOL ULTRA FLUIDE and have resuscitation equipment to hand.

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• Diuretics
In the event of dehydration provoked by diuretics, the risk of acute renal failure is increased, especially when high doses of iodinated contrast agents are used.
Precautions for use: re-hydration before administration of the iodinated contrast agent.
• Metformin
Lactic acidosis triggered by impaired renal function induced by the radiological investigation in diabetic patients.
Treatment with metformin must be suspended 48 hours before the investigation and only restarted 2 days after the radiological examination.
Associations to be taken into account
• Interleukin II
The risk of developing a reaction to the contrast agents is increased in the event of previous treatment with interleukin II (IV route): skin rash or, more rarely, hypotension, oliguria, or even renal failure.

Interference with diagnostic tests
Since LIPIODOL ULTRA FLUIDE remains in the body for several months, results of thyroid diagnostic tests may be distorted for up to two years after a lymphography.

PREGNANCY AND BREAST-FEEDING

Pregnancy

LIPIODOL ULTRA-FLUIDE must not be used in pregnant women because of the transplacental transfer of iodine, over a long period of time, which interferes probably with the thyroid function of the fœtus, with a potential risk of cerebral lesions and permanent.

It must not be used for hysterosalpingography when pregnancy is suspected or confirmed.

The occurrence of maternal hypothyroidism after hysterosalpingography procedure and the possible long half-life of the product in the event of a successful pregnancy requires a surveillance of the newborns thyroid function.

Lactation

Pharmacokinetic studies have shown significant secretion of iodine in breast milk after intramuscular administration of LIPIODOL ULTRA-FLUIDE. It has been demonstrated that the iodine enters the vascular system of the breastfed infant via the gastrointestinal tract and this could interfere with thyroid function. Consequently, breastfeeding should be discontinued if LIPIODOL ULTRA-FLUIDE must be used.

Effects on ability to drive and use machines

Not applicable.

Undesirable effects

-Most of the adverse reactions are dose-related and consequently the dose should be as low as possible.Use of LIPIODOL ULTRA-FLUIDE causes a foreign body reaction, with the formation of macrophages and foreign-body giant cells and the occurrence of sinus catarrh, plasmacytosis and subsequently changes in lymph node connective tissue. Healthy lymph nodes tolerate the resulting decrease in transport capacity. In patients with lymph node lesions or hypoplasia, these changes may exacerbate lymph stasis.

Hypersensitivity reactions are possible. These reactions may involve one or more effects, occurring concomitantly or successively, and usually including cutaneous, respiratory and/or cardiovascular manifestations, each of which can be a warning sign of incipient shock and, in very rare instances, can even prove fatal.

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 allergies.

Other dangers include oil embolism and venous intravasation.

A transient Lipiodol miliary is often observed on radiological images, particularly following a high or inappropriate dose. This usually remains clinically silent. In exceptional cases, pulmonary or cerebral embolism may be observed.
Spinal cord accidents are rare.

In Lymphography:
A large increase in temperature followed by a fever of 38 to 39°C may occur within 24 hours following the examination.
Fat micro-embolisms may occur, with or without symptoms. In very rare cases, they may resemble embolisms originating in the body, in terms of their appearance and size. They usually appear as punctiform opacities on radiographic images of the lungs. Transient increases in temperature are possible. Fat micro-embolisms usually occur following an overdose of contrast agent or excessively rapid infusion. Anatomic anomalies such as lymphovenous fistulas or a decrease in the capacity of lymph nodes to retain the contrast agent (in elderly patients or after radiotherapy or cytostatic therapy) favour their occurrence. Patients with a right-to-left cardiac shunt and those with a massive pulmonary embolism are particularly at risk for fat micro-embolisms in the brain.

In hysterosalpingography
Ttransitory fever reactions usually below 38°C accompanied by pelvic pain are frequent. Episodes of salpingitis or pelvic peritonitis have been reported after the exam in case of latent infection. Granuloma type tissue reactions are rare but could be serious during the exam as they produce a risk of perforation.

Hypothyroidism may also occur especially in patient with subclinical hypothyroidism. Following maternal exposure with LIPIODOL ULTRA FLUIDE, fetal thyroid disorders including fetal goitre were also reported.

Intravasation of LIPIODOL ULTRA FLUIDE may occur in the course of hysterosalpingography procedure and may result in serious pulmonary or cerebral embolic complications.

In interventional radiology:
• In Trans-Arterial Chemo-Embolisation
Most of the adverse reactions are not caused by LIPIODOL ULTRA-FLUIDE itself but are due to anticancer drugs or the embolisation itself.

The most frequent adverse reactions of the TACE treatment are post embolisation syndrome (fever, abdominal pain, nausea, vomiting) and transitory changes in liver function tests.

The worsening of a pre-existing hepatocellular insufficiency can occur following the use of LIPIODOL ULTRA-FLUIDE in the context of Trans-Arterial Chemo-Embolisation and may exceptionally lead to the occurrence of serious and potentially fatal complications such as hepatic encephalopathy, liver abscess, hepatic infarction, ascites, pancreatitis, or even necrotizing pancreatitis.

Further serious adverse events associated with uncontrolled dissemination of LIPIODOL ULTRA-FLUIDE in various organs includes pulmonary, cerebral (which could lead to cerebral infarction) or skin embolisms (which could lead to skin necrosis) may also occur. Massive pulmonary embolism has been associated with serious complications including

dyspnea, pulmonary oedema, pleural effusion, acute respiratory distress syndrome, and pneumonitis.

• Embolisation with surgical glues
Specific adverse reactions directly related to LIPIODOL ULTRA-FLUIDE have not been reported.

Frequencies of adverse effects
The adverse effects (regardless of indication) 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 <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000), unknown (cannot be estimated from the available data).

System organ class	Frequency: Adverse reactions
Immune system disorders	Unknown: hypersensitivity, anaphylactic reaction, anaphylactoid reaction
Endocrine disorders	Uncommon: hypothyroidism* Unknown: hyperthyroidism, thyroiditis, goitre**
Nervous system disorders	Unknown: cerebral embolism, cerebral infarction, hepatic encephalopathy
Skin and subcutaneous tissue disorders	Unknown: skin necrosis
Eye disorders	Unknown: retinal vein thrombosis
Vascular disorders	Unknown: lymphoedema aggravation
Respiratory, thoracic and mediastinal disorders	Unknown: pulmonary embolism, dyspnoea, cough, pulmonary oedema, pleural effusion, acute respiratory distress syndrome, pneumonitis
Gastrointestinal disorders	Unknown: vomiting, diarrhoea, nausea, pancreatitis, ascites
Hepatobiliary disorders	Unknown: hepatic vein thrombosis, cholecystitis, biloma, hepatic failure, hepatic infarction
Infections and infestations	Unknown: liver abscess
General disorders and administration site conditions	Unknown: granuloma, fever, pain
Injury, poisoning and procedural complications	Unknown: Venous intravasation**

*Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism.
** in the context of hysterosalpingography (HSG)

Adverse reactions in children
The types of adverse reactions to LIPIODOL ULTRA-FLUIDE are the same as those reported in adults. Their frequency cannot be estimated on the basis of available data.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

Overdose

Following intralymphatic injection, cardiorespiratory and central venous complications are proportional to the dose of LIPIODOL ULTRA-FLUIDE injected.
The total dose of LIPIODOL ULTRA-FLUIDE must not exceed 15 mL.

The treatment of an overdose involves immediate symptomatic treatment and maintenance of vital functions. Establishments performing examinations with contrast agents must have emergency medicines and equipment available.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

NON-WATER-SOLUBLE CONTRAST AGENTS, Code ATC: V08AD01
(V: Other)

Trans-Arterial Chemo-Embolisation
Used in Trans-Arterial Chemo-Embolisation by selective intra-arterial hepatic injection, LIPIODOL ULTRA-FLUIDE allows, as an oily contrast agent, the visualisation and control of the procedure thanks to its opacifying properties. As a vehicle, it carries and elutes anticancer drugs into hepatocellular carcinoma nodules and, as a transient embolic agent, it contributes to the vascular embolisation induced during the procedure.
As a selective intra-arterial hepatic injection procedure, Trans-Arterial Chemo-Embolisation combines the effect of a loco-regional targeted anticancer drug with the effect of an ischemic necrosis induced by dual arterio-portal embolisation. LIPIODOL ULTRA-FLUIDE's opacifying properties and tropism for hepatic tumours continues for several months, so post procedure imaging can be performed for an effective patient follow-up.

Pharmacokinetic properties

After intralymphatic injection

LIPIODOL ULTRA-FLUIDE is released into the blood, taken up by the liver and lungs where the oily droplets are degraded in the pulmonary alveoli, spleen and adipose tissue.

After being taken up by the tissues and storage organs, reabsorption of LIPIODOL ULTRA-FLUIDE occurs over a period lasting from a few days to several months or years. This is continuous and regular and the presence of iodides in the urine can be detected as long as contrast material is visible on the images.

After selective intra-arterial injection
The iodine is eliminated mainly in the urine. After selective intra-arterial injection into the hepatic artery for the diagnostic of hepatic lesions or in Trans-Arterial Chemo-Embolisation of hepatocellular carcinoma, LIPIODOL ULTRA-FLUIDE is significantly more concentrated in the tumour than in the healthy liver tissue.

Following intra-arterial administration of LIPIODOL ULTRA FLUIDE, the product retained in normal hepatic parenchyma is phagocytised by the Kupffer cells of the liver and washed out via the hepatic lymphatic system in about 2 to 4 weeks. In hepatocellular carcinoma (HCC), retention in the liver tumour is prolonged, allowing re-imaging of the tumour for four weeks or longer.

After intrauterine injection
After intrauterine injection in rats, LIPIODOL ULTRA FLUIDE migrates through the Fallopian tubes to the peritoneal cavity from which it is resorbed. The Tmax in plasma is reached around 8 hours post-administration. Half-life in plasma was about 18 hours. After 7 days, 48% of injected dose was eliminated (37% in urine, 11% in faeces).

Preclinical safety data

Not applicable.

PHARMACEUTICAL PARTICULARS

Incompatibilities

Plastic is not suitable for the storage of LIPIODOL ULTRA-FLUIDE. In the absence of any specific compatibility studies, plastic containers and syringes should not be used.

Shelf-life

3 years.

Special precautions for storage

Store below 30 and PROTECT FROM LIGHT

If the product becomes opaque or dark amber in color (approximately the color of a 1% solution of potassium dichromate), it should not be used.

Nature and contents of container

10 ml type I glass ampoule.
PRESENTATIONS
10 ml glass ampoule, box of 1
Not all pack size may be marketed

MANUFACTURER

MA. Holder adderss:

Guerbet

BP 57400, 95943 Roissy CdG cedex
FRANCE

Manufacturing address:
16-24 rue Jean Chaptal, 93600 Aulnay-sous-Bois
FRANCE

IMPORTER

P.T. Nicholas Laboratories Indonesia
Jln. Pulobuaran Raya Blok FF 12A
Jakarta Industrial Estate Pulogadung,
Jakarta 13930 Indonesia

DATE OF REVISION

(date of approval)

Reg No: DKI1279500943A1

HARUS DENGAN RESEP DOKTER
On Medical Prescription Only

PAKET LEAFLET: INFORMASI UNTUK PASIEN

Nama produk obat

LIPIODOL ULTRA FLUIDE (480 mgI /ml), larutan untuk injeksi
Etil ester asam lemak beryodium dari minyak biji poppy

Bacalah semua selebaran ini dengan seksama sebelum Anda mulai menggunakan obat ini karena mengandung informasi penting untuk Anda.

- Simpan selebaran ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan atau keraguan lebih lanjut, tanyakan kepada dokter, ahli radiologi , atau apoteker Anda untuk informasi lebih lanjut.
- Produk obat ini diresepkan khusus untuk Anda. Jangan berikan itu kepada orang lain. Ini dapat membahayakan mereka, bahkan jika tanda-tanda penyakitnya sama dengan Anda.
- Jika Anda mendapatkan efek samping, bicarakan dengan dokter, ahli radiologi, atau apoteker Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam selebaran ini. Lihat bagian 4.

Apa yang ada di selebaran ini?

1. APA ITU LIPIODOL ULTRA FLUIDE DAN KEGUNAANNYA?

Kelompok farmakoterapi: Agen kontras yang tidak larut dalam air – Kode ATC: V08AD01

LIPIODOL ULTRA FLUIDE termasuk dalam kelas agen kontras beryodium. LIPIODOL ULTRA FLUIDE meningkatkan kontras gambar yang diperoleh selama pemeriksaan ini, yang meningkatkan visualisasi dan penggambaran kontur bagian tubuh tertentu.

Ketika dicampur dengan obat-obatan tertentu yang digunakan untuk mengobati kanker, Cairan LIPIODOL ULTRA-FLUIDE membawa dan mengantarkan obat ke area yang akan dirawat.

Produk obat ini digunakan:

- Selama pemeriksaan radiologi.
- Selama operasi.
- Pada pemeriksaan radiologis rahim dan saluran telur saat mencari penyebab infertilitas.

2. YANG PERLU ANDA KETAHUI SEBELUM MENGGUNAKAN LIPIODOL ULTRA FLUIDE

Jangan gunakan LIPIODOL ULTRA FLUIDE:

- Jika Anda alergi terhadap zat aktif (etil ester asam lemak beryodium dari minyak biji poppy).
- Jika Anda pernah atau baru saja mengalami cedera parah atau pendarahan besar,
- Jika Anda memiliki hipertiroidisme, yaitu kelenjar tiroid yang terlalu aktif
- Selama pemeriksaan radiologi, Anda tidak boleh menerima suntikan produk obat ini:
  - Jika Anda perlu menjalani bronkografi (pemeriksaan radiologis bronkus di mana zat kontras diberikan langsung ke paru-paru).
- Selama operasi, produk obat ini tidak boleh disuntikkan:
  - jika Anda memiliki bekuan darah di vena hati
  - jika Anda memiliki saluran empedu yang membesar.
- Jika Anda hamil atau mengira Anda hamil dan akan menjalani histerosalpingografi (pemeriksaan rahim dan saluran telur),
- Jika Anda mengalami peradangan di panggul (perut bagian bawah) yang memengaruhi rahim, saluran tuba atau ovarium harus menjalani histerosalpingografi (pemeriksaan rahim dan saluran telur).

DISETUJUI OLEH BPOM: 10 OKTOBER 2022 ID EREG10028812100002

PRODUK OBAT INI TIDAK BOLEH DISUNTIKKAN KE ARTERI BESAR, VENA ATAU KOLOM VERTEBRAL.

Peringatan dan pencegahan

Bicaralah dengan dokter Anda sebelum menggunakan LIPIODOL ULTRA FLUIDE jika:

- Anda memiliki, atau pernah mengalami, gangguan alergi seperti:
  - alergi terhadap produk obat ini yang terjadi khususnya selama pemeriksaan radiologi sebelumnya,
  - alergi terhadap yodium,
  - jenis alergi lainnya (makanan, pewarna atau pengawet atau obat-obatan),
  - gatal-gatal,
  - bercak merah yang gatal (eksim),
  - asma,
  - demam alergi serbuk bunga.
- Anda memiliki penyakit jantung, pembuluh darah atau paru-paru (gagal jantung atau pernapasan, malformasi jantung).
- Anda memiliki penyakit ginjal (gagal ginjal).
- Anda memiliki pembuluh darah yang melebar di kerongkongan
- Anda penderita diabetes.
- Anda memiliki kadar kolesterol darah yang tinggi (hiperkolesterolemia).
- Anda sedang dalam perawatan atau baru saja dirawat karena kanker dengan obat-obatan (kemoterapi) dan/atau dengan radiasi (radioterapi).
- Anda memiliki kelainan tiroid.
- Anda dijadwalkan untuk pemeriksaan tiroid atau pengobatan dengan yodium radioaktif.
- Anda sedang hamil , berniat untuk hamil atau menyusui atau berencana untuk menyusui. Jika Anda menerima obat ini saat hamil, bayi Anda yang baru lahir harus diuji untuk memastikan mereka memproduksi jumlah hormon tiroid yang benar.
- Jika seluruh atau sebagian lengan atau kaki Anda bengkak, termasuk jari tangan atau kaki Anda (limfedema).
- Anda memiliki atau pernah mengalami salah satu dari kondisi medis berikut:
  - penyakit yang mempengaruhi hati Anda yaitu sirosis,
  - Anda memiliki masalah dengan saluran yang membawa empedu

Anak-anak

Tak dapat diterapkan.

Obat-obatan lain dan LIPIODOL ULTRA FLUIDE

Beri tahu dokter Anda jika Anda sedang mengonsumsi, baru saja mengonsumsi, atau mungkin sedang mengonsumsi:

- Obat untuk mengobati penyakit jantung atau tekanan darah tinggi (beta-blocker, diuretik).
- Obat untuk mengobati diabetes (metformin).
- Interleukin-2, obat untuk mengobati kanker atau memperkuat sistem kekebalan tubuh.
- Obat-obatan yang Anda ketahui beracun bagi ginjal (misalnya antibiotik atau antivirus tertentu)

Jika Anda sedang mengonsumsi atau baru saja mengonsumsi obat lain, termasuk yang tidak memerlukan resep medis, beri tahu dokter atau apoteker Anda.

LIPIODOL ULTRA FLUIDE dengan makanan dan minuman

Reaksi antara LIPIODOL ULTRA FLUIDE dan makanan atau minuman belum dilaporkan. Namun, Anda harus bertanya kepada dokter atau ahli radiologi Anda apakah Anda tidak boleh makan atau minum sebelum menerima produk obat ini.

Kehamilan dan menyusui

Kehamilan

Mintalah saran dari dokter, ahli radiologi , atau apoteker Anda sebelum minum obat apa pun.

Jika perlu, dokter Anda mungkin meresepkan yodium selama kehamilan.

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LIPIODOL ULTRA FLUIDE tidak boleh diberikan kepada Anda jika Anda sedang hamil atau mengira Anda hamil dan akan menjalani histerosalpingografi (pemeriksaan rahim dan saluran telur).

Menyusui

Mintalah saran dari dokter atau apoteker Anda sebelum minum obat apa pun.

Anda harus berhenti menyusui jika harus mengonsumsi produk obat ini.

Mengemudi dan menggunakan mesin

LIPIODOL ULTRA FLUIDE seharusnya tidak mempengaruhi kemampuan Anda untuk mengemudi atau menggunakan mesin. Namun, jika Anda merasa tidak enak badan setelah mengonsumsi produk obat ini, sebaiknya Anda tidak mengemudi atau menggunakan mesin.

3. CARA MENGGUNAKAN LIPIODOL ULTRA FLUIDE

Dosis

Dosis tergantung pada alasan penggunaannya.

Dokter Anda akan menentukan dosis yang akan disuntikkan.

Cara dan rute pemberian

Seorang profesional kesehatan akan mempersiapkan dan menyuntikkan produk ini sebelum melakukan pemeriksaan.

Rute dan metode injeksi tergantung pada alasan pemberian produk obat.

Anda akan dipantau untuk setiap efek samping selama setidaknya 30 menit setelah injeksi.

Anda mungkin diberikan antibiotik untuk mencegah infeksi yang terjadi dari prosedur.

Saat dibuka, obat ini harus digunakan sekali saja dan residunya dibuang.

Durasi pengobatan

Obat ini biasanya diberikan hanya sekali. Namun, pemberian dapat diulang jika perlu.

Jika Anda telah menggunakan lebih banyak LIPIODOL ULTRA FLUIDE dari yang seharusnya

Tak dapat diterapkan.

Jika Anda lupa menggunakan LIPIODOL ULTRA FLUIDE

Tak dapat diterapkan.

Jika Anda berhenti menggunakan LIPIODOL ULTRA FLUIDE

Tak dapat diterapkan.

4. MUNGKIN EFEK SAMPING

Seperti semua obat-obatan, produk obat ini dapat menyebabkan efek samping, meskipun tidak semua orang mendapatkannya.

Reaksi alergi dapat terjadi. Mereka ditunjukkan oleh tanda-tanda berikut:

Kemerahan, jerawat, gatal dan/atau pembengkakan tiba-tiba pada wajah, kelopak mata, bibir atau tenggorokan yang dapat mengakibatkan kesulitan bernapas atau menelan. Tanda-tanda lain yang mungkin dari reaksi alergi adalah: mengi, hidung tersumbat, bersin, batuk, tenggorokan kering, gatal-gatal.

Dalam kasus luar biasa, reaksinya mungkin serius. Jika salah satu dari tanda-tanda ini terjadi, Anda harus segera menghubungi dokter Anda.

Efek samping lain yang mungkin terjadi adalah:

- Demam tinggi beberapa jam setelah pemeriksaan.
- Gangguan gastrointestinal seperti mual, muntah, diare, radang pankreas.
- Nyeri dan nyeri pada panggul (perut bagian bawah) .
- Peningkatan ukuran kelenjar tiroid Anda
- Penyumbatan pembuluh darah tertentu di paru-paru (emboli paru), yang dapat menyebabkan retensi cairan yang berlebihan di paru-paru (edema paru) dan di sekitarnya (efusi pleura), gagal napas kritis (sindrom gangguan pernapasan akut), pulmonitis , sesak napas. nafas, batuk

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- Penyumbatan pembuluh darah tertentu di otak.
- Memburuknya limfedema (pembengkakan yang disebabkan oleh fungsi sistem limfatik yang salah)
- Lesi hati yang mengakibatkan gangguan fungsi hati, akumulasi cairan di perut (asites), suplai darah yang tidak mencukupi ke hati (infark hati) dan tingkat kesadaran yang berubah, mungkin terkait dengan gejala neurologis lainnya (ensefalopati hepatik).
- Tanda-tanda fungsi tiroid yang berlebihan seperti penurunan berat badan, detak jantung lebih cepat dan transit usus, gugup dan insomnia.
- Massa berisi nanah di hati.
- Peradangan kandung empedu.
- Penumpukan empedu di perut (biloma).
- Nekrosis kulit.
- Sindrom pasca embolisasi (demam, sakit perut, mual dan muntah) dapat terjadi setelah pemberian LIPIODOL ULTRA-FLUIDE selama transarterial . kemoembolisasi (oklusi pembuluh darah yang memberi makan tumor menggunakan terapi obat yang ditargetkan).
- Peradangan pada saluran telur atau peritoneum.
- Sejumlah kecil LIPIODOL ULTRA FLUIDE dapat bocor ke suplai darah dan berakhir di bagian lain dari tubuh seperti pembuluh darah atau arteri.
- Pembengkakan berbagai bagian tubuh (kaki, lengan)
- Setelah histerosalpingografi, demam sementara dengan nyeri di daerah panggul sering dicatat serta kemungkinan salpingitis (radang saluran tuba) atau pelvioperitonitis (radang rongga perut atau rongga panggul) jika ada infeksi laten.

Pelaporan efek samping

Jika Anda mendapatkan efek samping, bicarakan dengan dokter, ahli radiologi, atau apoteker Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam selebaran ini. Anda juga dapat melaporkan efek samping secara langsung melalui sistem pelaporan nasional.
Anda mungkin membutuhkan tindakan medis secepatnya. Lakukan ini bahkan jika tidak ada tanda-tanda ketidaknyamanan atau keracunan. Anda mungkin membutuhkan tindakan medis secepatnya.

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

5. CARA MENYIMPAN LIPIODOL ULTRA FLUIDE

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan gunakan LIPIODOL ULTRA FLUIDE setelah tanggal kedaluwarsa yang tertera pada karton. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.

Simpan di bawah suhu 30°C dan terlindung dari cahaya.

Jangan membuang produk obat melalui air limbah atau dengan limbah rumah tangga.

Tanyakan apoteker Anda bagaimana membuang produk obat yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. ISI PAKET DAN INFORMASI LAINNYA

Apa kandungan LIPIODOL ULTRA FLUIDE

- Zat aktifnya adalah:

  Etil ester asam lemak beryodium minyak biji poppy (kadar yodium: 48%, yaitu 480 mg/mL).
- LIPIODOL ULTRA FLUIDE tidak mengandung bahan lain selain zat aktif.

Seperti apa LIPIODOL ULTRA FLUIDE dan isi kemasannya

LIPIODOL ULTRA FLUIDE adalah cairan berminyak bening berwarna kuning pucat.

Produk obat ini adalah solusi untuk injeksi dalam 10 ml ampul.

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7. PABRIKAN

Alamat Pemegang MA:

Guerbet
BP 57400, 95943 Roissy CdG Cedex
Perancis

Alamat pembuatan:

16-24 rue Jean Chaptal, 93600 Aulnay-sous-Bois
Perancis

PENGIMPOR

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Jln . Pulobuaran Raya Blok FF 12A
Kawasan Industri Jakarta Pulogadung ,
Jakarta 13930 Indonesia

8. TANGGAL REVISI

Nomor Reg:

HARUS DENGAN RESEP DOKTER
Hanya Dengan Resep Medis