PROPOSED CLEAN COPY PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, strength and pharmaceutical form

LIPIODOL® ULTRA FLUID (480 mg I/ml), solution for injection

Ethyl esters of iodised fatty acids of poppy seed oil

Sugar free

Read all of this leaflet carefully before you are given LIPIODOL® ULTRA FLUID

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, radiologist or pharmacist for more information.
- LIPIODOL® ULTRA FLUID has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LIPIODOL® ULTRA FLUID is and what it is used for

LIPIODOL® ULTRA FLUID belongs to the class of iodinated contrast agents. LIPIODOL® ULTRA FLUID enhances the contrast of images obtained during radiological examinations which improves the visualisation and delineation of the contours of certain parts of the body. When mixed with certain medicines used to treat cancer, LIPIODOL® ULTRA FLUID carries and delivers the medicine into the area to be treated.

When it is used

LIPIODOL® ULTRA FLUID is used:

- During radiological examinations
- During surgery

2. What you need to know before you are given LIPIODOL® ULTRA FLUID

You should not be given LIPIODOL® ULTRA FLUID:

- if you are allergic to the active substance (ethyl esters of iodised fatty acids of poppy seed oil) or iodine.
- during radiological examinations, you must not receive an injection of LIPIODOL® ULTRA FLUID:
  - if you have elevated serum levels of thyroid hormones (hyperthyroidism)
  - if you have or recently have had wounds with significant bleeding
  - if you are pregnant
  - if you are scheduled for bronchography (radiological examination of the bronchia during which the contrast agent is administered directly to the lungs).
- during surgery, LIPIODOL® ULTRA FLUID must not be injected if you have a blood clot in a liver vein.

LIPIODOL® ULTRA FLUID MUST NOT BE INJECTED INTO LARGE ARTERIES, VEINS OR THE VERTEBRAL COLUMN.

Warnings and precautions

Tell your doctor or health care provider before being given the injection if:

- you have, or have had, and allergic disorder such as:
  - allergy to LIPIODOL® ULTRA FLUID that occurred in particular during previous radiological examinations
  - allergy to iodine
  - any other kind of allergy (dietary or medicinal)
  - asthma
  - hives
  - red patches that itch (eczema)
  - hay fever
- you have heart, blood vessels or lung disease (heart or respiratory failure, cardiac malformation)
- you have kidney disease (renal failure)
- you have dilated veins in the oesophagus
- you are diabetic
- you have high levels of blood cholesterol (hypercholesterolaemia).
- you are currently under treatment or have recently been treated for cancer with medicines (chemotherapy) and/or with radiation (radiotherapy)
- you have a thyroid disorder
- you are scheduled for a thyroid examination or treatment with radioactive iodine.

Other medicines and LIPIODOL® ULTRA FLUID

Tell your doctor if you are taking, have recently taken or might take:

- A medicine to treat heart disease or high blood pressure (beta-blockers, diuretics)
- A medicine to treat diabetes (metformin)
- Interleukin-2, a medicine to treat cancer or reinforce the immune system.

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

LIPIODOL® ULTRA FLUID with food and drink

Reactions between LIPIODOL® ULTRA FLUID and food or drink have not been reported. However, you should ask your doctor or radiologist if you should not eat or drink before receiving LIPIODOL® ULTRA FLUID.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or health care provider for advice before taking any medicine.

You should stop breastfeeding if you are given LIPIODOL® ULTRA FLUID.

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 LIPIODOL® ULTRA FLUID, you should not drive or use machines.

3. How to receive LIPIODOL® ULTRA FLUID

You will not be expected to give yourself LIPIODOL® ULTRA FLUID. It will be given to you by a person who is qualified to do so.

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 care provider will prepare and inject LIPIODOL® ULTRA FLUID before carrying out the examination.

The route and method of injection depends on the reason for which LIPIODOL® ULTRA FLUID is being administered.

Duration of treatment

LIPIODOL® ULTRA FLUID is usually administered only once. However, administration can be repeated if necessary.

4. Possible side effects

LIPIODOL® ULTRA FLUID can have side effects.

Not all side effects reported for LIPIODOL® ULTRA FLUID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LIPIODOL® ULTRA FLUID, please consult your doctor, radiologist or pharmacist for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing and breathing
- rash or itching
- fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to LIPIODOL® ULTRA FLUID. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- 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 insomnia.
- pains.
- blockage of certain blood vessels in the lungs or brain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, radiologist or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LIPIODOL® ULTRA FLUID.

5. How to store LIPIODOL® ULTRA FLUID

KEEP OUT OF REACH OF CHILDREN.

Store at or below 25 °C, in the original package, protected from light.

Do not use LIPIODOL® ULTRA FLUID after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LIPIODOL® ULTRA FLUID contains

The active substance of LIPIODOL® ULTRA FLUID is ethyl esters of iodised fatty acids obtained from poppy seed oil (iodine content: 48 %, 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

1 x 10 ml ampoule containing a light yellow tinted coloured fluid.

Holder of certificate of registration

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