

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

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.

Solution for injection in 5 ml or 10 ml ampoules.

Pharmaco-therapeutic class

Contrast agent.

Guerbet

BP 57400

95943 ROISSY CdG Cedex - FRANCE

When to use this medicinal product (therapeutic indications)

This medicinal product is an iodinated contrast agent. It has been prescribed to you for a radiological examination which is to be performed for diagnostic purposes or during a surgical procedure.

It can also be used to prevent iodine deficiency disorders when iodization of salt or drinking water cannot be undertaken.

WARNINGS !

When not to use this medicinal product (contraindications)

In radiology

This product MUST NOT BE ADMINISTERED by general intra-arterial, intravenous or intrathecal injection (injection of the product via the same route as for lumbar puncture).

In the treatment of iodine deficiency

This medicinal product MUST NOT BE USED in the following situations:

- if you suffer from hyperthyroidism,
- if you have a large, multinodular goiter and are aged over 45 years, due to the high risk of hyperthyroidism,
- if you are breast-feeding,

Special warnings

In diagnostic or interventional radiology

You should inform the doctor who is to perform the injection if you have or have had any problems of an allergic nature:

- allergic reactions to iodinated products, particularly during previous radiological examinations with contrast agents,
 - food or drug-related allergies,
 - urticaria,
 - eczema,
 - asthma,
 - hay fever.
- Or if you suffer from cardiac or respiratory insufficiency.
 - Or if you have a liver (cirrhosis) or thyroid disorder.

In iodine deficiency

Do not associate with other methods of iodine supplementation (iodization of salt or drinking water) which could increase the risk of hyperthyroidism.

It is advisable to avoid using this medicinal product in persons over the age of 45 years.

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE

Precautions for use

A premature polymerisation reaction may exceptionally occur between Lipiodol Ultra-Fluide and certain glues or batches of glues. Prior to any use of new batches of Lipiodol Ultra-Fluide or glue, it is mandatory to verify in vitro the compatibility between the glue used and Lipiodol Ultra-Fluide.

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE

Interactions with other medicinal products and other forms of interaction

IN ORDER TO AVOID ANY INTERACTIONS BETWEEN DIFFERENT MEDICINAL PRODUCTS, YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU ARE TAKING especially any treatment for hypertension or diabetes.

Pregnancy - Lactation

In iodine deficiency

If you are pregnant, your doctor may prescribe you iodine supplementation.

Due to the risk of hypothyroidism in neonates, Lipiodol is contraindicated during breast-feeding.

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE

AS A GENERAL RULE, IF YOU ARE PREGNANT OR BREAST-FEEDING, YOU SHOULD ALWAYS ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST BEFORE TAKING ANY MEDICINAL PRODUCT.

HOW TO USE THIS MEDICINAL PRODUCT

Dosage

Dosage varies according to the indication and is determined by the doctor performing the injection.

Method and route of administration

This product must be administered using a glass syringe.

In diagnostic radiology

Lymphography: intralymphatic injection only

Diagnosis of liver lesions: selective intra-arterial injection only

In interventional radiology

Embolization with surgical glues: selective intra-arterial injection only

In iodine deficiency

Intramuscular injection only

Duration of treatment

This medicinal product will be administered to you in a single dose.

UNDESIRABLE EFFECTS

AS WITH ALL ACTIVE PRODUCTS, THIS MEDICINAL PRODUCT MAY CAUSE SOME UNDESIRABLE EFFECTS OF VARIABLE INTENSITY IN CERTAIN PERSONS:

possible onset of allergic reactions.

In diagnostic radiology

You may experience transient fever during the first few hours following the examination.

You may experience gastrointestinal disorders (nausea, vomiting or diarrhoea)

In iodine deficiency

You may present signs of hyperthyroidism (weight loss, accelerated heart rate, increased intestinal transit rate, anxiety, insomnia, etc.).

PLEASE REPORT ANY UNDESIRABLE EFFECT WHICH IS NOT MENTIONED IN THIS LEAFLET TO YOUR DOCTOR OR PHARMACIST.

STORAGE

Do not use the product after the expiry date indicated on the outer packaging.

Special precautions for storage

Store protected from light.

DATE LEAFLET LAST REVISED

03/11/2005.

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