

LIPIODOL ULTRA FLUID

Iodised Oil Fluid Injection

Presentation

Solution for Injection. LIPIODOL is a sterile, pale yellow colour iodised oil fluid presented in 10 mL ampoules. It contains ethyl esters of iodised fatty acids of poppy seed oil, 480mg of iodine per mL. Total iodine 4.8g per 10mL (38% m/m).

Uses

Actions

LIPIODOL is an X-ray contrast medium for use in certain radiological investigations where it is desirable to outline a viscous or other structure with directly instilled radio-opaque material. On account of its low viscosity LIPIODOL is suitable for introduction into narrow channels and may therefore be used in ducts and sinuses.

Pharmacokinetics

From most sites in the body LIPIODOL is slowly absorbed, but from the peritoneal cavity (after hysterosalpingography) absorption is relatively rapid. Following intralymphatic administration, LIPIODOL is transported in the blood to the liver, to the lungs where the lipid droplets are rapidly dispersed in the pulmonary alveoli, to the spleen and to the adipose tissue. Disappearance of droplets in the lungs or other tissues proceeds slowly. During metabolism, iodine is released which is eliminated in urine as iodine. LIPIODOL can remain in the body for several weeks or months after lymphography.

Indications

LIPIODOL is used in lymphography, hysterosalpingography (however water soluble agents are preferred) and sialography.

Dosage and Administration

The medium should be administered via a suitable syringe and cannula, the volume to be administered depending on the technique being carried out and the

size of the patient. LIPIODOL may be used for children or elderly patients at the physician's discretion.

Contraindications

LIPIODOL is unsuitable for bronchography as it would rapidly fill the bronchioles and the alveoli. The medium is contraindicated in cases of recent haemorrhage.

Warnings and Precautions

Care should be taken in those subjects presenting a history of previous allergic manifestations or of thyroid dysfunction. The injection of the medium into certain fistulae should be conducted with great care in order to avoid penetration of vascular channels and the possibility of oil embolism. Iodism occurs more frequently with LIPIODOL than with water-soluble iodine derivatives. LIPIODOL should be used with care in patients with impaired lung function. The administration of iodine-containing contrast media may interfere with thyroid function tests for periods of 3 months or more.

The product should only be used in patients with iodine hypersensitivity if the benefits likely to be derived outweigh the risks entailed, and if adequate facilities are available for control of immediate and delayed reactions.

The product should be administered using a glass syringe.

Pregnancy

There is no evidence that this product is safe during pregnancy nor is there evidence in animal work that it is free from hazard. The product should not be used during pregnancy unless the benefit outweighs the risk and is considered essential by the physician. The ten day rule in women of child bearing age should be observed.

Adverse Effects

The risk of hypersensitivity reactions or iodism is greater after the use of iodised oil than after water-soluble iodinated contrast media. Pulmonary oil embolism is reported to be relatively frequent following lymphangiography but is not usually severe; however, hypotension, tachycardia, pulmonary odema, and infarction may occur rarely and deaths have been reported in patients with pulmonary disease. Chemical pneumonitis, odema, granuloma formation, and goitre have been observed.

Interactions

The administration of iodised oil may interfere with thyroid-function tests for several months.

Overdosage

Gross overdosage is most unlikely to occur in lymphography. Complications and adverse reactions are more frequent with the higher doses. Treatment of adverse effects is symptomatic.

Pharmaceutical Precautions

Shelf Life

36 months

Special Precautions for Storage

Store below 25°C. Protect from light. If the product becomes opaque or dark amber in colour it should not be used.

Incompatibilities

The product should be administered using a glass syringe. Plastic is not suitable for the storage of LIPIODOL. In the absence of any specific compatibility studies, plastic containers and syringes should not be used.

Medicine Classification

General Sales Medicine

Package Quantities

1 x 10 mL ampoule

Name and Address

Distributed in New Zealand by:

Obex Medical Limited
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