

January 2024

## LIPIODOL ULTRA FLUID

iodine (as ethyl esters of iodized fatty acids of poppy seed oil), 480 mg/ml **מרכיב פעיל:**

**רופא/ה, רוקח/ת נכבד/ה,**

בעל הרישום פרומדיקו בע"מ – מקבוצת ניאופרם – מבקש להודיע על עדכון העלון של התכשיר שבנדון.  
העלון עודכן בתאריך ינואר 2024.

### ההתוויה הרשומה לתכשיר בישראל:

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

### העדכונים העיקריים בעלון הנם:

**מקראה:**

מידע שהוסר - מסומן בקו אדום חוצה **XXX**

תוספת - כתב **כחול**

#### 4.4. Special warnings and precautions for use

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##### Disturbed thyroid function

Due to their free iodine content, iodinated contrast agents may alter thyroid function and thus cause hyperthyroidism in predisposed patients. Patients at risk are those with latent hyperthyroidism and those with thyroid autonomy. Iodism occurs more frequently with LIPIODOL ULTRA FLUIDE than with water-soluble organic derivatives of iodine.

Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been reported following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism. See also section on Paediatric population.

Paediatric population:

~~Special attention should be paid to paediatric patients below 3 years of age because an incident underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient T4 replacement therapy. The incidence of hypothyroidism in patients younger than 3 years of age exposed to iodinated contrast media has been reported between 1.3% and 15% depending on the age of the subjects and the dose of the iodinated contrast agent and is more commonly observed in neonates and premature infants. Neonates may also be exposed through the mother during pregnancy. Thyroid function should be evaluated in all paediatric patients younger than 3 years of age following exposure to iodinated contrast media. If hypothyroidism is detected, the need for treatment should be considered and thyroid function should be monitored until normalized.~~

##### Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age

Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media (ICM) in pediatric patients 0 to 3 years of age.

Younger age, very low birth weight, prematurity, underlying medical conditions affecting thyroid function, admission to neonatal or pediatric intensive care units, and congenital cardiac conditions are associated with an increased risk of hypothyroidism after ICM exposure. Pediatric patients with congenital cardiac conditions may be at the greatest risk given that they often require high doses of contrast during invasive cardiac procedures.

An underactive thyroid during early life may be harmful for cognitive and neurological development and may require thyroid hormone replacement therapy. After exposure to ICM, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates.

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### Special warnings for transarterial chemoembolisation

Transarterial chemoembolisation is not recommended in patients with decompensated cirrhosis of the liver (Child-Pugh  $\geq 8$ ), severe hepatic dysfunction, macroscopic portal vein invasion, portal thrombosis (partial or total), and/or extrahepatic tumour dissemination.

An intra-arterial hepatic procedure may cause irreversible liver failure in patients with severe hepatic dysfunction and/or treated over several sessions close together. Tumour invasion of greater than 50% of the liver, bilirubin levels over 2 mg/dl, lactate dehydrogenase levels over 425 mg/dl, aspartate aminotransferase levels over 100 IU/l and decompensated cirrhosis have been described as being associated with an increase in the post-procedure mortality rate.

Oesophageal varices should be monitored carefully as they may rupture immediately after treatment. If a risk of rupture is identified, an endoscopic sclerotherapy/ligation should be performed prior to the transarterial chemoembolisation procedure.

Iodinated contrast-induced renal failure risk should be prevented by systematic hydration before and after the procedure.

The risk of superinfection in the treated area can be prevented by the administration of antibiotics.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום פרומדיקו בע"מ, בנין ניאופרם, רחוב השילוח 6 ת.ד. 7063 פתח תקוה 4917001, טלפון: 03-9373737, פקס: 03-9373770

בברכה,

אבי ילצינדג

רוקח ממונה