

September 2023

## LIPIODOL ULTRA FLUID

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

רופא/ה, רוקח/ת נכבד/ה,

בעל הרישום פרומדיקו בע"מ – מקבוצת ניאופרם – מבקש להודיע על עדכון העלון לרופא של התכשיר שבנדון.  
העלון עודכן בתאריך ספטמבר 2023.

ההתוויה הרשומה לתכשיר בישראל:

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

**מקראה לעדכונים המסומנים:**

מידע שהוסר - מסומן בקו אדום חוצה **XXX**  
תוספת - כתב **כחול**

**עדכונים מהותיים נעשו בסעיף הבא בעלון לרופא:**

### 4.4. Special warnings and precautions for use

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#### Disturbed thyroid function

#### Thyroid

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.

~~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-FLUID than with water-soluble organic derivatives of iodine.~~

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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