

January 2024

## XENETIX 250 / XENETIX 300 / XENETIX 350

מרכיב פעיל: iobitridol, 250 mg/ml ; 300 mg/ml ; 350 mg/ml

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 לתכשירים בישראל:

### XENETIX 250

For adults and children undergoing: phlebography, chest CT scan, intra - arterial digital subtraction angiography.

### XENETIX 300 / XENETIX 350

For adults and children undergoing: intravenous urography, brain or whole body CT scan, intravenous digital subtraction angiography, arteriography, angiocardiography.

**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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##### 4.4.1.2.5. Disturbed thyroid function

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:

##### 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.

~~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.~~

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#### 4.8. Undesirable effects

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The following adverse reactions were reported for other water-soluble iodinated contrast agents:

System Organ Class	Frequency: adverse reaction
Nervous system disorders	Paralysis, paresis, <b>hallucinations</b> , speech disorders
Psychiatric disorders	<b>Hallucinations</b>
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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