

September 2023

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, angiocardiology.

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 Dysthyroidism

~~Following the injection of an iodinated contrast agent, particularly in patients with a goitre or a history of dysthyroidism, there is a risk of either hyperthyroidism flaring up or hypothyroidism being induced. There is also a risk of hypothyroidism in newborns who have received, or whose mother has received, an iodinated contrast agent.~~

~~Consequently, thyroid function in newborns should be evaluated and monitored to check that it is normal.~~

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.

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4.6. Fertility, pregnancy and lactation

Pregnancy

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In neonates who have been exposed to iodinated contrast media in utero, it is recommended to monitor thyroid function (see section 4.4).

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4.8. Undesirable effects

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System Organ Class	Frequency: adverse reaction
...	...
Endocrine disorders	Very rare: thyroid disorders Not known: transient neonatal hypothyroidism ₁ <u>hypothyroidism***</u>

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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