

01/2024

אומניפאק 240

אומניפאק 300

אומניפאק 350

OMNIPAQUE 240

OMNIPAQUE 300

OMNIPAQUE 350

מרכיבים פעילים:

IOHEXOL 518 MG/ML

IOHEXOL 647 MG/ML

IOHEXOL 755 MG/ML

צורת מינון:

SOLUTION FOR INJECTION

רופא/ה, חוקח/ת נכבד/ה,

חברת אלדן ציוד אלקטרוני בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.
העלון עודכן בתאריך ינואר 2024.

ההתוויה הרשומה לתכשיר בישראל:

X-ray contrast medium for use in adults and children for cardioangiography, arteriography, urography, phlebography and CT- enhancement. Lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection.

Arthrography, endoscopic retrograde pancreatography (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography and studies of the gastrointestinal tract.

מקראה לעדכונים המסומנים:

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

תוספת - כתב **כחול**

תוספת חמרה - רקע **צהוב**

העדכון בעלון לרופא:

4.4 Special warnings and precautions for use.

(...)

Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age Paediatric population:

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.



מכון התקנים הישראלי

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.

(...)

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום
אלדן ציוד אלקטרוני בע"מ, בנין ניאופרם, רח' השילוח 6 ת.ד. 7641 פתח תקוה 4917001, טלפון: 03-9371111, פקס:
03-9371100.

בברכה,

עוז וולך

רוקח ממונה