

09/2023

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, רוקח/ת נכבד/ה,
חברת אלדן ציוד אלקטרוני בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.
העלון עודכן בתאריך ספטמבר 2023.

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.

בהודעה זו מצוינים השינויים המהותיים בלבד.

מקראה לעדכונים המסומנים:

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

תוספת - כתב כחול

תוספת חמרה - כתב כחול-מסומן בצהוב מרקר

מידע שעבר מקום - כתב ירוק

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

4.4 Special warnings and precautions for use.

(...)

Observation-time:

Patients must be kept under close observation for 30 minutes following the last injection as the majority of severe reactions occur at this time.

The patient should remain in the hospital environment (but not necessarily the radiology department) for one hour after the last injection, and should return to the radiology department if any symptoms develop.

(...)

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.

~~Transient hypothyroidism has been reported in premature infants, neonates and in other children after administration of iodinated contrast media.—Premature infants are particularly sensitive to the effect of iodine. It is advisable to monitor thyroid function. Thyroid function should be checked in neonates during the first week of life, following administration of iodinated contrast agents to the mother during pregnancy. Repeat testing of thyroid function is recommended at 2 to 6 weeks of age, particularly in low birth weight newborn or premature newborn.~~

(...)

4.6 Fertility, pregnancy and lactation

(...)

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

4.8 Undesirable effects

(...)

General (applies to all uses of iodinated contrast media)

(...)

Injury, poisoning and procedural complications:

Not known: Iodism

Intravascular use (Intraarterial and Intravenous use)

(...)

Nervous system disorders:

(...)

Not known: Transient motor dysfunction (including speech disorder, aphasia, dysarthria), transient contrast induced encephalopathy (including transient memory loss, disorientation, coma, retrograde amnesia), **hemiparesis**, and disorientation, brain oedema.)

(...)

Skin and subcutaneous tissue disorders:

Rare: Rash, pruritus, urticaria

Not known: Bullous dermatitis, Stevens-Johnson syndrome, **erythema multiforme**, toxic epidermal necrolysis, acute generalised exanthematous pustulosis, drug rash with eosinophilia and systemic symptoms, psoriasis flare-up, erythema, drug eruption, skin exfoliation.

(...)

Renal and urinary **system** disorders:

Uncommon: Acute kidney injury

Not known: Blood creatinine increased

Rare: Impairment of renal function including acute renal failure

Intrathecal use

(...)

Nervous system disorders:

Very common: Headache (may be severe and prolonged)

Uncommon: Aseptic meningitis (including chemical meningitis) .

Rare: Seizures, dizziness

Not known: Electroencephalogram abnormal, meningism, status epilepticus, transient contrast-induced encephalopathy (including transient memory loss, coma, stupor, retrograde amnesia, **hemiparesis**), motor dysfunction (including speech disorder, aphasia, dysarthria), paraesthesia, hypoesthesia and sensory disturbance

(...)

Eye disorders:

Rare: Visual impairment (including diplopia and blurred vision)

Not known: Transient cortical blindness, photophobia

(...)

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

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