**05/2023**

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|---|---|
| **OMNIPAQUE 240** | **אומניפאק 240** |
| **OMNIPAQUE 300** | **אומניפאק 300** |
| **OMNIPAQUE 350** | **אומניפאק 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 מאי 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**

**עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:**

**4.4 Special warnings and precautions for use.**
**Special precautions for use of non-ionic monomeric contrast media in general:**
**(...)**
Patients using ~~β~~ **beta**-blockers **blocking agents, particularly asthmatic patients, may have a lower threshold for bronchospasm and are less responsive to treatment with beta agonists and adrenaline, which may necessitate the use of higher doses. These patients** may present with atypical symptoms of anaphylaxis which may be interpreted as vagal reaction.
**(...)**
**Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiocardiographic procedures with both ionic and non-ionic contrast media.** When performing vascular catheterization procedures one should pay meticulous attention to the angiographic technique and flush the catheter frequently (e.g.: with heparinized saline) so as to minimize the risk of procedure-related thrombosis and embolism. The examination shall be kept as short as possible. Care should be taken in patients with homocystinuria. (Risk for thromboembolism).

**(...)**

**CNS disturbances:**

**(…)**

**Encephalopathy has been reported with the use of contrast media, such as iohexol (see section 4.8). Contrast encephalopathy may manifest with symptoms and signs of neurological dysfunction such as headache, visual disturbance, cortical blindness, confusion, seizures, loss of coordination, hemiparesis, aphasia, unconsciousness, coma and cerebral oedema. Symptoms usually occur within minutes to hours after administration of iohexol, and generally resolve within days.**

**Factors which increase blood-brain barrier permeability will ease the transfer of contrast media to brain tissue and may lead to possible CNS reactions for instance encephalopathy.**

**(…)**

**If contrast encephalopathy is suspected, administration of iohexol should be discontinued and appropriate medical management should be initiated.**

**(…)**

~~**Normal serum creatinine (<130µ mol/litre)/normal renal function: Administration of metformin should be stopped at the time of administration of contrast medium and should not be resumed for 48 hours and only be restarted if renal function/serum creatinine remains in the normal range.**~~

~~**Abnormal serum creatinine (>130µ mol/litre)/impaired renal function: Metformin should be stopped and the contrast medium examination delayed for 48 hours. Metformin should only be restarted 48 hours later if renal function is not diminished (if serum creatinine is not increased) compared to pre-contrast values.**~~

**(1) Patients with eGFR equal or greater than 60 ml/min/1.73m2 (CKD 1 and 2) can continue to take metformin normally.**

**(2) Patients with eGFR 30-59 ml/min/1.73m2 (CKD 3)**

- **Patients receiving intravenous contrast medium with eGRF equal or greater than 45 ml/min /1.73m2) can continue to take metformin normally**
- **In patients receiving intra-arterial contrast medium, and those receiving intravenous contrast medium with an eGFR between 30 and 44 ml/min/1.73m2 metformin should be discontinued 48 hours before contrast medium and should only be restarted 48 hours after contrast medium if renal function has not deteriorated.**

**(3) In patients with eGFR less than 30 ml/min/1.73m2 (CKD 4 and 5) or with an intercurrent illness causing reduced liver function or hypoxia metformin is contraindicated iodinated contrast media should be avoided.**

**(4)** In emergency cases where renal function is impaired or unknown, the physician should evaluate the risk/benefit of the contrast medium examination, and the following precautions should be implemented: Metformin should be stopped. It is particularly important that the patient is fully hydrated prior to contrast medium administration and for 24 hours afterwards. Renal function (e.g. serum creatinine), **serum lactic acid and blood pH should be monitored, as well as the patient with regard to signs of lactacidosis.**

**A pH <7.25 or a lactic acid level of >5 mmol/litre are indicative of lactic acidosis. The patient should be observed for symptoms of lactic acidosis. These include vomiting, somnolence, nausea, epigastric pain, anorexia, hyperpnoea, lethargy, diarrhoea and thirst. Metformin should be restarted 48 hours after contrast medium if serum creatinine/eGFR is unchanged from the pre-imaging level.**

**(…)**

Disturbed thyroid function:

**(…)**

~~**Following injection of an iodinated contrast agent, there is also a risk of induction of hypothyroidism.**~~

**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 Pediatric population.**

**(…)**

Paediatric population:

~~**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.**~~

**Hypothyroidism or transient thyroid suppression may be observed after exposure to iodinated contrast media. Special attention should be paid to pediatric 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% dependingon the age of the subjects and the dose of the iodinated contrast agent and is more commonly observed in neonates and premature infants. Thyroid function should be evaluated in all pediatric patients younger than 3 years of age within 3 weeks following exposure to iodinated contrast media, especially in premature infants and neonates. If hypothyroidism is detected, thyroid function should be monitored as appropriate even when replacement treatment is given.**

**(…)**

**4.8 Undesirable effects**

**(…)**

Immune system disorders:

Rare: Hypersensitivity **(may be life-threatening or fatal)** (including dyspnoea, rash, erythema, urticaria, pruritus, skin reaction, conjunctivitis, coughing, rhinitis, sneezing, vasculitis, angioneurotic oedema, laryngeal oedema, laryngospasm, bronchospasm or non-cardiogenic pulmonary oedema). They may appear immediately after the injection or up to a few days later and may be indicative of the beginning of a state of shock. Hypersensitivity related skin reactions may appear up to a few days after the injection.

**Very rare: Anaphylactic /anaphylactoid reaction (may be life-threatening or fatal)**

Not known: Anaphylactic /anaphylactoid reaction, **Anaphylactic**/anaphylactoid shock **(may be life-threatening or fatal)**

Nervous system disorders:

~~**Uncommon**~~ **Rare**: Headache

Very rare: Dysgeusia (transient metallic taste) **Syncope vasovagal**

~~**Not known: Syncope vasovagal**~~

**(…)**

Gastrointestinal disorders:

Uncommon: Nausea

Rare: Vomiting, **abdominal pain**

Very rare: Diarrhoea, ~~**abdominal pain/discomfort**~~

Not known: Salivary gland enlargement

**(…)**

Eye disorders:

Rare: Visual impairment **(including diplopia and blurred vision)**

Not known: Transient cortical blindness

**(...)**

Cardiac disorders:

Rare: Arrhythmia (including bradycardia, tachycardia).

Very rare: myocardial infarction, **chest pain**

Not known: Severe cardiac complications (including cardiac arrest, cardio-respiratory arrest), cardiac failure, spasm of coronary arteries, cyanosis ~~**chest pain**~~

**(...)**

Gastrointestinal disorders:

Rare: Diarrhoea

Not known: Aggravation of pancreatitis, ~~**acute pancreatitis**~~

Skin and subcutaneous tissue disorders:

Rare: Rash, pruritus, urticaria

Not known: **Angioedema**, 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**

Rare: **Blood creatinine increased** ~~**Impairment of renal function including acute renal failure**~~

**(...)**

Psychiatric disorders:

Not known: Confusion, agitation, **anxiety**

**(...)**

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