נובמבר 2024

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון:

Ultravist 300
Ultravist 370
Iporomide solution for injection

אנו מבקשים להודיעכם שהעלון לרופא של התכשירים שבנדון עודכן.

ההתוויה המאושרת לתכשיר:
Contrast enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, arteriography, phlebography of the extremities, venography, visualization of body cavities (e.g.arthrography, hysterosalpingography, fistulography) with the exception of myelography, ventriculography, cisternography.

בהודעה זו כלולים העידכונים המהותיים בלבד, בפירוט שלהלן מופיע, רק המידע שהתעדכן. תוספת טקסט מודגשת בצבע אדום ומסומנת בקו תחתון.

לתשומת ליבכם, המידע במלואו מופיע בעלון לרופא אשר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug
כמו כן, ניתן לקבלו מודפס ע"י פניה לחברת באייר ישראל, רח' החרש 36 הוד השרון, טלפון: 09-7626700

העדכונים בעלון לרופא:

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
~~There are no other absolute contraindications to Ultravist use.~~

4.4 Special warnings and precautions for use

4.4.1.5 Hydration

Good hydration must be ensured in all patients before ~~and after~~intravascular Ultravist administration ~~to limit the risk of contrast medium induced nephrotoxicity~~(see also section "Intravascular use" – "~~Renal function impairment~~Acute kidney injury"). This applies especially to patients presenting renal impairment risk factors, such as patients with multiple myeloma, diabetes, polyuria, oliguria or hyperuricaemia, and to newborns, babies, ~~infants~~toddlers, young children and elderly patients.
Adequate hydration must be ensured in patients presenting renal impairment. However, the prophylactic administration of intravenous fluid in patients with moderate renal impairment (eGFR 30-59 mL/min./1.73 m^2) is not recommended as no additional benefit in terms of renal safety has been demonstrated. In patients with severe renal impairment (eGFR < 30 mL/min./1.73 m^2) and cardiac comorbidity, the prophylactic administration of intravenous fluid can lead to an increase in serious cardiac complications. See sections 4.4.2.1 *Acute kidney injury*, 4.4.2.2 *Cardiovascular disorders* and 4.8.2 *Summary table of*

undesirable effects. If prophylactic intravenous fluids are administered, monitoring of cardiac function parameters is recommended.

4.4.2 Intravascular use

4.4.2.1 ~~Renal function impairment~~**Acute kidney injury**

Post-contrast acute kidney injury (PC-AKI) can occur after intravascular administration of Ultravist, manifesting in the form of temporary renal impairment~~After intravascular administration of Ultravist contrast medium induced nephrotoxicity may occur, presenting as transient renal function impairment~~. Acute kidney injury may also occur in a few cases.

The main risk factors are:

- pre-existing renal impairment (see section 4.2 Patients with renal impairment)
- dehydration (see section 4.4.1.5 Hydration)
- diabetes
- multiple myeloma/paraproteinaemia,
- repeated and/or high doses of Ultravist.

Patients with moderate to severe renal impairment (eGFR 44-30 mL/min./1.73 m^2) or severe renal impairment (eGFR < 30 mL/min./1.73 m^2) are at increased risk of post-contrast acute kidney injury (PC-AKI) during arterial administration of contrast media with first-pass renal exposure.
Patients with severe renal impairment (eGFR < 30 mL/min./1.73 m^2) are at increased risk of PC-AKI when administration is intravenous or intraarterial with second-pass renal exposure (see section 4.4.1.5 Hydration).
~~Good hydration must be ensured in all patients who receive Ultravist.~~

Patients on dialysis and without residual renal function may receive Ultravist for radiological examinations because the iodinated contrast medium is cleared by dialysis.
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4.4.3 Contrast-enhanced mammography **(CEM)**

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4.5 Interaction with other medicinal products and other forms of interaction

Biguanides (metformin): in patients with acute kidney injury or severe chronic kidney disease, biguanide elimination may be disrupted, leading to accumulation and the development of lactic acidosis. As the use of Ultravist may lead to renal impairment or aggravation of renal impairment, patients treated with metformin may be at an increased risk of developing lactic acidosis, especially those with pre-existing renal impairment (see section "Special warnings and precautions for use" – under 'Intravascular use' – 'Acute kidney injury'~~"Renal function impairment"~~). ~~Based on liver function under tests, the need to stop the metformin treatment should be considered.~~ The administration of metformin should be discontinued temporarily, at the latest from the time of administration of the iodinated contrast medium, in patients with eGFR < 30 ml/min./1.73 m^2 when administration is intravenous or intraarterial with second pass renal exposure to the iodinated contrast media, or in patients with eGFR < 45 ml/min./1.73 m^2 when administration is with first pass renal exposure. Metformin should be resumed 48 hours after administration of the contrast medium if serum creatinine/eGFR has not changed from the pre-imaging levels. If the eGFR is higher than these values, the metformin may be continued provided hydration is adequate.
Interleukin-2: previous interleukin-2 treatment (up to several weeks previously) is associated with an increase in the risk of delayed reactions to Ultravist.

Radioisotopes: the diagnosis and treatment of thyroid disorders with thyrotropic radioisotopes may be impeded for several weeks after the administration of Ultravist due to reduced radioisotope uptake.

Nephrotoxic medicines: the use of nephrotoxic medicines (for example NSAIDs, aminosides, cisplatin) should be discontinued temporarily when examining patients with eGFR < 30 ml/min./1.73 m^2 in the case of intravenous or intraarterial administration with second pass renal exposure to iodinated contrast media, or in patients with eGFR < 45 ml/min./1.73 m^2 in the case of first pass renal exposure.