דצמבר 2021

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון:
Ultravist 300+370
Solution for injection
Iopromide 623.4/768.86 mg/ml

אנו מבקשים להודיעכם שהעלון לרופא של התכשירים שבנידון עודכן.

ההתוויה המאושרת לתכשיר:

Ultravist 300:
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.

Ultravist 370:
Contrast enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, arteriography and especially angiocardiography, visualization of body cavities (e.g. arthrography, fistulography) with the exception of myelography, ventriculography, cisternography.

בהודעה זו כלולים העדכונים המהותיים בלבד. בפירוט שלהלן מופיע, מתוך כל פרק ששונה בעלון, רק המידע שהתעדכן. תוספת טקסט מסומנת בקו תחתון. מחיקת טקסט מסומנת ~~בקו חוצה~~.

העדכונים בעלון לרופא

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4.1 Therapeutic indication

This medicinal product is for diagnostic use only.

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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 the use of Ultravist.

4.4 Special warning and precautions for use

4.4.1.2 Severe skin reactions

Severe skin reactions, particularly cases of Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) and acute generalised exanthematous pustulosis (AGEP) that may be life-threatening or fatal have been associated with iopromide administration at a frequency that is not known.

Patients must be informed of the associated signs and symptoms and close monitoring for the onset of skin reactions is required.

In children, the skin rash observed initially may be misinterpreted as an infection, and physicians should consider the possibility of a reaction to iopromide in children who develop signs of skin rash and fever.

In most cases, these reactions occurred within 8 weeks (1 to 12 days for AGEP, 2 to 8 weeks for DRESS syndrome, and 5 days to 8 weeks for SJS/TEN).

If the patient develops a serious reaction such as SJS, TEN, AGEP or DRESS syndrome during iopromide use, iopromide must never be readministered.

4.4.1.3 Thyroid dysfunction

In patients with known or suspected hypothyroidism or goitre, a very careful risk/benefit assessment is necessary because the iodinated contrast medium may cause hyperthyroidism and a thyrotoxic crisis in these patients. In patients with known or suspected hyperthyroidism, testing of thyroid function and/or a prophylactic thyrostatic medicinal product should be considered before Ultravist administration.

Thyroid function tests indicating hypothyroidism or a transient decrease in thyroid function have been reported following administration of iodinated contrast media in adult and paediatric patients. The potential risk of hypothyroidism must be evaluated in patients with known or suspected thyroid disease prior to the use of iodinated contrast media.

In newborn babies, especially premature infants, who have been exposed to Ultravist either through the mother during pregnancy or in the neonatal period, monitoring of thyroid function is recommended because exposure to an excessive amount of iodine may cause hypothyroidism, possibly requiring treatment.

4.4.1.4 CNS disorders

Patients with CNS disorders may be at an increased risk of neurological complications following Ultravist administration. Neurological complications are more common in the context of cerebral angiography and related procedures.

Cases of encephalopathy have been reported following the use of iopromide (see section 4.8). Contrast media-induced encephalopathy may manifest as signs and symptoms of neurological dysfunction, such as headache, vision disorders, cortical blindness, confusion, seizures, loss of coordination, hemiparesis, aphasia, loss of consciousness, coma, and cerebral oedema. Symptoms generally appear within a few minutes or hours of iopromide administration and generally resolve within a few days.

Caution should be exercised in situations in which there may be a reduced seizure threshold, as in patients with a history of epileptic episodes and in the concomitant use of specific medicinal products.

Factors which increase blood-brain barrier permeability promote the passage of the contrast medium into cerebral tissue, which may induce CNS reactions such as encephalopathy.

If contrast media-induced encephalopathy is suspected, appropriate medical care must be given and iopromide must never be readministered to this patient.

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Table 1: Undesirable effects reported in clinical trials or in the post-marketing period in patients treated with Ultravist

System organ class	Common	Uncommon	Rare	Frequency unknown
Immune system disorders		Hypersensitivity/ anaphylactoid reactions (anaphylactoid shock§)*), respiratory arrest§)*), bronchospasm*), laryngeal*)/ pharyngeal*)/facial oedema, tongue oedema§), laryngeal/pharyngeal		

System organ class	Common	Uncommon	Rare	Frequency unknown
		spasm[§)], asthma[§)*)], conjunctivitis[§)], lacrimation[§)], sneezing, cough, mucosal oedema, rhinitis[§)], hoarseness[§)], throat irritation[§], urticaria, pruritus, angioedema)		
Endocrine disorders				Thyrotoxic crisis, thyroid disorders
Psychiatric disorders			Anxiety	
Nervous system disorders	Dizziness, headaches, dysgeusia	Vasovagal reactions, confused state, restlessness, paraesthesia/ hypoesthesia, somnolence		Coma[*)], cerebral ischaemia/infarction[*)], cerebrovascular accident[*)], cerebral oedema[a)*)], convulsions[*)], transient loss of cortical vision[a)], loss of consciousness, agitation, amnesia, tremor, speech disorders, paresis/paralysis, contrast media-induced encephalopathy
Eye disorders	Vision disorder/ visual acuity disorder			
Ear and labyrinth disorders				Hearing disorders
Cardiac disorders	Chest pain/ discomfort	Arrythmia[*)]	Cardiac arrest[*)], myocardial ischaemia[*)], palpitations	Myocardial infarction[*)], heart failure[*)], bradycardia[*)], tachycardia, cyanosis[*)]
Vascular disorders	Hypertension, vasodilation	Hypotension[*)]		Shock[*)], thromboembolic events[a)], vasospasm[a)]
Respiratory, thoracic and mediastinal disorders		Dyspnoea[*)]		Pulmonary oedema[*)], respiratory failure[*)], aspiration[*)]
Gastrointestinal disorders	Vomiting, nausea	Abdominal pain		Swallowing disorders, swelling of the salivary

System organ class	Common	Uncommon	Rare	Frequency unknown
				glands, diarrhoea
Skin and subcutaneous tissue disorders				Bullous disorders (e.g. Stevens-Johnson or Lyell syndrome), rash, erythema, hyperhidrosis, acute generalised exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms
Musculoskeletal and connective tissue disorders				Compartment syndrome in the case of extravasation[a)]
Renal and urinary disorders				Renal disorders[a)], acute kidney injury[a)]
General disorders and administration site conditions	Pain, injection site reactions (of various types such as pain, feeling of warmth[§)], oedema[§)], inflammation[§)], soft tissue lesions[§)] in the case of extravasation), hot flushes	Oedema		Feeling faint, shivering, pallor
Investigations				Fluctuation in body temperature

[*)] life-threatening and/or fatal cases have been reported
[a)] during intravascular use only
[§)] identified only during post-marketing surveillance (frequency not known)

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp
ניתן לקבלו מודפס ע"י פניה לחברת באייר ישראל, רח' החרש 36 הוד השרון, טלפון: 09-7626700.

בברכה,
באייר ישראל