מרץ 2024

Iopamiro 300, 370, Solution for Injection

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים יופמירו 300, 370.

בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלון.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

הרכב התכשיר:

Each ml of solution contains iopamidol 612.4 mg or 755.3 mg respectively.

התוויות מאושרות:

X-ray contrast medium in neuroradiology, angiography, urography, ct scanning, arthrography and fistulography.

העלון לרופא עודכן בפברואר 2024. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום)**:**

4.3 Contraindications

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~~The concomitant intrathecal administration of corticosteroids with Iopamidol is contraindicated (see section 4.5 Interaction with other medicinal products and other forms of interaction).~~

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4.4 Special warnings and special precautions for use

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Hydration

Patients must be well hydrated and any relevant abnormalities of fluid or electrolyte balance must be corrected before and after injection of contrast media. Especially patients with severe impairment of kidney, liver or myocardial function, with myelomatosis or other paraproteinemias, with sickle-cell anaemia, diabetes mellitus, polyuria, oliguria, hyperuricemia, infants, elderly and patients with severe systemic diseases should not be exposed to dehydration. Caution should be exercised when hydrating patients with underlying conditions that may be aggravated by fluid overload, including congestive heart failure.

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Phaeochromocytoma

Patients with phaeochromocytoma can develop severe hypertensive crises following intra-arterial iopamidol administration. Premedication with α and β receptor blockers is recommended before the contrast media intra-arterial administration under medical supervision.

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Iopamidol should be administered with caution in patients with heart attack, problems with the CNS and abnormal permeability of the blood-brain barrier, for example increased intracranial pressure, suspicion of intracranial tumour, abscess or hematoma/haemorrhage, previous seizures, alcoholism.

Intrathecal administration

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The concomitant administration of iodinated contrast medium with a corticosteroid may increase the risk of neurotoxicity and aseptic meningitis.

An accurate evaluation of the risk/benefit ratio is required in patients with known CNS problems.

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Use in Special Populations

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Women of child-bearing potential - X-ray examinations in women should be carried out during the pre-ovulation phase of the menstrual cycle if possible and should be avoided during pregnancy; moreover, as Iopamirus has not been shown to be safe for use in pregnant women, it should only be administered only if the procedure is considered essential by the doctor.

Iopamiro contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

To prevent onset of lactic acidosis in diabetic patients being treated with oral anti-diabetic agents of the biguanide class (metformin), these agents should be discontinued prior to intra-

arterial administration of contrast medium with first-pass renal exposure, or in patients with acute kidney injury, and only reinstituted after 48 hours if renal function has not changed significantly. (See 4.4 Special warnings and precautions for use: Special populations).

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Beta-blockers may impair the management of bronchospasm and the response to adrenaline.

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Consider stopping treatment with drugs that lower the epileptogenic threshold up to 24 hours after the procedure for intrathecal use and for patients with blood-brain barrier disorders (see section 4.4 Special warnings and precautions for use).

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4.8 Undesirable effects

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Intravascular administration

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	Adverse Reactions			
	Clinical Trials			Post-marketing Surveillance
System Organ Class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Frequency unknown*
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Skin and subcutaneous tissue disorders				Stevens-Johnson syndrome, Toxic epidermal necrolysis, Erythema multiforme, skin necrosis****
Musculoskeletal and connective tissue disorders				Compartment syndrome****
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General disorders and administration site conditions			Swelling at injection site	Inflammation at injection site****

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****In rare occasions, extravasation of contrast medium causes inflammation (manifested locally by erythema, oedema and vesicles), skin necrosis and compartment syndrome.

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