

ספטמבר 2022

## Iopamiro 300, 370, Solution for Injection

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים: איופמירו 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 בספטמבר 2022. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

#### 4.4 Special warnings and precautions for use

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The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis.

General anaesthesia may be indicated in selected patients. However, a higher incidence of adverse reactions has been reported in these patients, probably due to the hypotensive effect of the anaesthetic.

As with all other contrast media this product may provoke anaphylaxis or other manifestations of allergy with nausea, vomiting, dyspnoea, erythema, urticaria and hypotension. Occasional severe reactions with fatal outcome have been reported.

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Pre-treatment with antihistamines or corticosteroids to prevent or minimise possible allergic reactions in such patients may be considered.

The risk of bronchospasm-inducing reactions in asthmatic patients is higher after contrast media administration, especially in patients taking beta-blockers.

In patients with suspected or known hypersensitivity to contrast media, sensitivity testing is not recommended, as severe or fatal reactions to contrast media are not predictable from sensitivity tests.

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Patients with severe hepatic, renal or combined hepato-renal insufficiency should not be examined unless absolutely indicated. Re-examination should be delayed for 5-7 days.

Care should be taken in renal impairment and diabetes. In these patients it is important to maintain hydration in order to minimize deterioration in renal function.

The presence of renal damage in diabetic patients is one of the factors predisposing to renal impairment following contrast media administration. This may precipitate lactic acidosis in patients who are taking metformin (see section 4.5 - Interaction with medicaments and other forms of interaction).

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Iopamiro should be administered with caution in elderly patients, in patients with symptomatic cerebrovascular diseases, recent stroke, or frequent TIA, altered permeability of the blood-brain barrier, increased intracranial pressure, suspicion of intracranial tumour, abscess or hematoma/hemorrhage, history of convulsive disorder, chronic alcoholism or multiple sclerosis. Patients with these conditions have an increased risk of neurological complications.

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### *Use in Special Populations*

#### Newborns, children

Infants (age < 1 year), and especially newborns are particularly susceptible to electrolyte imbalances and haemodynamic alterations. Care should be taken regarding the dosage to be used, the details of the procedure, and the patient's status.

When examining small children or babies, do not limit fluid intake before administering a hypertonic contrast solution. Also, correct any existing water and electrolyte imbalance.

In paediatric roentgenology, one should proceed with great caution when injecting the contrast medium into the right heart chambers of cyanotic neonates with pulmonary hypertension and impaired cardiac function.

Transient hypothyroidism may occur in neonates when the mother or the neonate has received an iodinated contrast agent. Thyroid function tests (usually TSH and T4) are recommended in neonates 7-10 days and 1 month after exposure to Iopamiro especially in preterm neonates.

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## **4.5 Interactions with other medicinal products and other forms of interaction**

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To prevent onset of lactic acidosis in diabetic patients under treatment with oral anti-diabetic agents of the biguanide class and with moderate renal impairment undergoing elective procedures, biguanides should be stopped 48 hours prior to the administration of the contrast medium and re-instated only after 48 hours if serum creatinine is unchanged. (See section 4.4 Special warnings and precautions).

In emergency patients in whom renal function is either impaired or unknown, the physician shall weigh out risk and benefit of an examination with a contrast medium. Metformin should be stopped from the

time of contrast medium administration. After the procedure, the patient should be monitored for signs of lactic acidosis. Metformin should be restarted 48 hours after contrast medium if serum creatinine/eGFR is unchanged from the pre-imaging level.

Patients with normal renal function can continue to take Metformin normally.

Arterial thrombosis has been reported when Iopamidol was given following papaverine.

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In patients receiving beta-blockers there is an elevated risk of more severe anaphylactoid reactions.

Beta-blockers may impair the response to treatment of bronchospasm induced by contrast medium.

The administration of vasopressors strongly potentiates the neurological effect of the intra-arterial contrast media.

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#### 4.6 Fertility, pregnancy and lactation

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Iodine-containing X-ray contrast agents are excreted into the breast milk in low amounts. From animal experience, Iopamiro is non toxic in animals after oral administration. From experience gained so far, harm to the nursing infant is unlikely to occur. Stopping breastfeeding is unnecessary.

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#### 4.8 Undesirable effects

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More severe reactions involving the cardiovascular system such as vasodilatation with pronounced hypotension, tachycardia, dyspnoea, agitation, cyanosis and loss of consciousness progressing to respiratory and/or cardiac arrest may result in death. These events can occur rapidly and require full and aggressive cardio-pulmonary resuscitation.

Primary circulatory collapse can occur as the only and/or initial presentation without respiratory symptoms or without other signs or symptoms outlined above.

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