מרץ, 2023

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.

<u>הרכב התכשיר:</u>

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

<u>התוויות מאושרות:</u>

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

העלון לרופא עודכן במרץ 2023. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

4.3 Contraindications

Hypersensitivity to the active substance and the water-soluble contrast media or to any of the excipients listed in section 6.1.

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4.4 Special warnings and special precautions for use

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The use of organic iodinate contrast media should be limited to cases for which there is a precise need for contrastographic examination.

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Contrast media designed for angiocardiographic procedures should be used in hospitals or clinics equipped and staffed for intensive care in emergencies .

For other more common diagnostic procedures calling for the use of iodinated contrast media, in the radiology departments of public or private clinics, where such procedures are to take place, resuscitation equipment and therapeutic measures should be immediately available (AMBU, oxygen, antihistaminic, vasoconstrictors, cortisonics, etc.).

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Conditions exposing to a greater risk of serious adverse events

In all the following conditions, due to the increased risk of serious adverse events, a careful evaluation of the risk-benefit ratio is recommended prior to treatment.

Patients with increased risk include those for which there is a suspicion of previous reactions to contrast or iodinated media and those suffering from allergic diseases (bronchial asthma, hay fever or food allergies).

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Key preventive measures include identification of high-risk patients, ensuring adequate hydration prior to contrast agent administration, preferably maintaining the intravenous infusion before and during the procedure, until the contrast medium has not been eliminated by kidneys; avoid administration of nephrotoxic drugs or undergoing the patient to major surgery or procedures such as renal angioplastic, until the contrast medium has not been completely eliminated by the kidneys;

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Contrast induced encephalopathy

Encephalopathy has been reported with the use of iopamidol (see section 4.8). This 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 within minutes to hours after administration and generally resolves 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, iopamidol should not be re-administered and appropriate medical management should be initiated.

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Iopamidol should be administered with caution in patients with symptomatic cerebrovascular disease, heart attack/recent stroke or transient ischemic attack (TIA), abnormal permeability of the blood-brain barrier, increased intracranial pressure, suspicion of intracranial tumour, abscess or hematoma/haemorrhage, previous seizures, alcoholism.

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Angiography

The risk associated with a particular investigation may be increased by conditions such as advanced arteriosclerosis, hypertension, heart failure, severe systemic disease, embolism or recent cerebral thrombosis.

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The intravascular injection of a contrast medium can evolve in pulmonary oedema in patients with congestive heart failure.

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Even in abdominal angiography excessive pressure transmitted by the automatic pump can cause renal infarction, spinal cord injury, retroperitoneal haemorrhage, myocardial and intestinal necrosis.
In peripheral arteriography using Iopamiro 370 mg/mL Solution for injection can cause the onset of painful effects that are not manifest with Iopamiro 300 mg/mL Solution for injection.

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Severe cutaneous adverse reactions

Severe cutaneous adverse reactions (SCARs), such Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (Lyell's syndrome or TEN) and acute generalised exanthematous pustulosis (AGEP), which can be life threatening, have been reported in patients administered with Iopamiro (see section 4.8, undesirable effects). At the time of initiation, patients should be advised of the signs and symptoms and monitored closely for severe skin reactions. If signs and symptoms suggestive of these reactions appear, further use of Iopamiro should be withheld. If the patient has developed a severe cutaneous adverse reaction with the use of Iopamiro, Iopamiro must not be re-administered in this patient at any time.

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Use in Special Populations
Newborns, children
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Transient thyroid suppression or hypothyroidism has been observed in children after exposure to iodinated contrast media.
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If hypothyroidism is detected, the need for treatment should be considered and thyroid function should be monitored until normalised.

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4.5 Interaction with other medicinal products and other forms of interaction

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Following administration of iopamidol atypical adverse reactions e.g. erythema, fever and flu symptoms have been reported in patients treated with interleukin-2 and interferon.

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Intrathecal administration

Alcoholism or drug addiction increase the permeability of the blood brain barrier. This facilitates the passage of iodinated agents in brain tissue with possible CNS disorders. A possible lowering of seizure threshold should be kept in mind.

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4.6 Fertility, pregnancy and lactation

Pregnancy

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Animal studies do not indicate direct or indirect effects on pregnancy and embryonal/fetal development. Caution is needed in prescribing the contrast medium in pregnant women.

Lactation

Iodine-containing X-ray contrast agents are excreted into the breast milk in low amounts. At therapeutic doses harmful effects on the nursing infant are unlikely. However, although no side effects in nursing infants have been reported, caution should be exercised when administering endovascular X-ray contrast media to nursing women because of potential adverse events and discontinuation of breastfeeding for 24 hours after treatment with iodinated contrast should be considered.

Fertility

There are no adequate and controlled clinical trials on fertility.

4.7 Effects on ability to drive and use machines

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Before driving or operating machinery, side effects such as hypotension, dizziness, confusion, shortness of breath, which may occur with the use of this medicinal product, should be taken into account.

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4.8 Undesirable effects

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Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with Iopamiro administration (see section 4.4).

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Intravascular administration

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Frequency unknown

Metabolism and nutrition disorders: Acidosis, Anorexia

Nervous system disorders: … Amnesia, Paralysis, Sleepiness, Tremors, Hemiplegia, Contrast induced encephalopathy

Eye disorders: … Ocular itching, Increased tear secretion

Ear and labyrinth disorders: Auditory deficit

Cardiac disorders: … Heart failure, Angina pectoris, Cyanosis, … Kounis syndrome

Vascular disorders: … Thromboembolismus, Arterial thrombosis, Venous thrombosis, Thrombophlebitis …

Skin and subcutaneous tissue disorders: … Periorbital oedema, Acute generalised exanthematous pustulosis (AGEP)

Renal and urinary disorders: Anuria, Urinary retention, Renal failure (including acute renal failure and renal damage), Oliguria, Hematuria, Urinary incontinence

Investigations: … increased T-wave amplitude, prolonged QT), Decreased systolic blood pressure, Electrolyte imbalances

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Accidents during the procedure could lead to pseudoaneurysm and/or peripheral embolism or cause bruising at the site of administration.

Brachial plexus injury can occur due to axillary artery injection.

Other cardiac reactions which may occur as a consequence of the procedural hazard include coronary artery dissection.

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Paediatric patients

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Cases of transient neonatal hypothyroidism have been reported with Iopamidol in very low birth weight infants.

Intrathecal administration

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Uncommon (≥1/1,000 to <1/100)

Skin and subcutaneous tissue disorders: … Hyperhidrosis

Frequency unknown

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Metabolism and nutrition disorders: Acidosis

Psychiatric disorders: Hallucinations, … Depression, … Anxiety, Irritability

Nervous system disorders: … Myelitis, … Vertigo, … Radicular pain, Drowsiness, Tremors, Muscle spasms, Contrast induced encephalopathy**

Eye disorders: … Conjunctivitis, Photophobia, Increased tear secretion, Itchy eyes

Ear and labyrinth disorders: Auditory deficit, Tinnitus

Cardiac disorders: … Tachycardia, Cyanosis

Respiratory, thoracic and mediastinal disorders: … Apnoea, Respiratory Failure …

Musculoskeletal and connective tissue disorders: Muscular weakness

Renal and urinary disorders: Renal failure (including acute renal failure), Urinary retention, Hematuria, Urinary incontinence

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Also less common than after intravascular administration are the respiratory (dyspnoea or respiratory distress in the form of bronchospasm) and mucocutaneous reactions (urticaria, angioneurotic oedema and other skin reactions such as rash).

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Paediatric patients

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Cases of transient neonatal hypothyroidism have been reported with Iopamidol in very low birth weight infants.

Use in body cavities

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The reactions reported in cases of arthrography and fistulography usually represent irritative manifestations superimposed on existing tissue inflammation.

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4.9 Overdose

Most side effects (see Section 4.8) are not dose-dependent and may therefore require therapeutic interventions as specified in Section 4.4.

In the event of voluntary or accidental administration of higher than normal doses, excretion should be facilitated by ensuring patient hydration, as clearance almost totally occurs via the kidney. In the event of renal insufficiency, whether pre-existing or manifesting after contrast medium introduction, dialysis will eliminate the contrast medium.

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6. Pharmaceutical Particulars

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6.2 Incompatibilities

Contrast media must not be mixed with other medicinal products, except for heparin.