

יוני 2022

Iomeron 300, 350, 400 mg, Solution for Injection

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים: אימרון 300, 350, 400.

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 100 ml of solution contains iomeprol 61.24 g, 71.44 g, 81.65 g respectively.

התוויות מאושרות:

Contrast medium for diagnostic radiology.

Iomeron 300: Intravenous urography (in adults and paediatrics), peripheral phlebography, CT (brain and body), cavernosography, intravenous DSA, conventional angiography, intraarterial DSA, angiocardiology (in adults and paediatrics), conventional selective coronary arteriography, interventional coronary arteriography, ERCP, arthrography, hysterosalpingography, fistulography, discography, galactography, cholangiography, dacryocystography, sialography, retrograde urethrography, retrograde pyelo-ureterography.

Iomeron 350: Intravenous urography (in adults and paediatrics), CT (body), intravenous DSA, conventional angiography, intraarterial DSA, angiocardiology (in adults and paediatrics), conventional selective coronary arteriography, interventional coronary arteriography, arthrography, hysterosalpingography, fistulography, galactography, retrograde cholangiography, dacryocystography, sialography.

Iomeron 400: Intravenous urography (in adults including those with renal impairment or diabetes), CT (body), conventional angiography, intraarterial DSA, angiocardiology (in adults and paediatrics), conventional selective coronary arteriography, interventional coronary arteriography, fistulography, galactography, dacryocystography, sialography.

העלון לרופא עודכן ביוני 2022. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

4.4 Special warnings and precautions for use

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Hydration

Patients must be well hydrated, and any relevant abnormalities of fluid or electrolyte balance should be corrected prior to **and following** contrast media injection. Especially patients with diabetes mellitus, polyuria, oligouria, hyperuricaemia, infants, small children and elderly patients, should not be exposed to dehydration. **Also patients with severely compromised hepatic and renal impairment are more at risk. Caution should be exercised in hydrating patients with underlying conditions that may be worsened by fluid overload, including congestive heart failure.**

Rehydration prior to use of iomeprol is recommended in patients with sickle cell disease.

Special population

Hypersensitivity to iodinated contrast media, allergic predisposition

A positive history of allergy, asthma or untoward reaction during previous similar investigations indicates a need for extra caution since, as with other contrast media, this product may provoke anaphylaxis or other manifestations of allergy with nausea, vomiting, dyspnoea, erythema, urticaria and hypotension. The benefits should clearly outweigh the risks in such patients and appropriate resuscitative measures should be immediately available. **The primary treatments are as follows:**

Effect	Major Symptoms	Primary Treatment
Vasomotor effect	warmth nausea/vomiting	reassurance
Cutaneous	scattered hives severe urticaria	H ₁ -antihistamines H ₂ -antihistamines
Bronchospastic	wheezing	oxygen Beta-2-agonist inhalers
Anaphylactoid reaction	angioedema urticaria bronchospasm hypotension	oxygen IV fluids adrenergics (iv epinephrine) Inhaled beta-2-adrenergics antihistamines (H ₁ -and H ₂ - blockers) corticosteroids
Hypotensive	hypotension	iv fluids
Vagal reaction	hypotension bradycardia	iv fluids iv atropine

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CNS Disorders

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Neurological symptoms related to **cerebrovascular diseases**, intracranial tumours/metastases or degenerative or inflammatory pathologies may be exacerbated.

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Renal impairment

In patients with moderate to severe impairment of renal function, attention should be paid to renal function parameters before re-examining the patient with a contrast media.

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Diabetes mellitus

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Children: Infants up to 1 year, especially the newborn, are particularly susceptible to electrolyte imbalance and haemodynamic alterations. Care should be taken regarding the dosage used.

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 Iomeron especially in preterm neonates.

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4.8 Undesirable Effects

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4.8.1 Intravascular administration

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Adults

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Blood and lymphatic system disorders: *Unknown:* Thrombocytopenia, **Haemolytic anaemia**

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Cardiac disorders: *Rare:* Bradycardia, Tachycardia, **Extrasystoles**

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Skin and subcutaneous tissue disorders: *Unknown:* **Acute generalized exanthematous pustulosis**,
Angioedema, Cold sweat, Sweating increased

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4.8.2 Administration to body cavities

After injection of an iodinated contrast media in body cavities, contrast media are slowly absorbed from the area of administration into the systemic circulation and subsequently cleared by renal elimination.

Blood amylase increased is common following ERCP. Very rare cases of pancreatitis have been described.

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

Hypersensitivity reactions are rare, generally mild and in the form of skin reactions. However, the possibility of severe anaphylactoid reactions cannot be excluded.

As with other iodinated contrast media, pelvic pain and malaise may occur after hysterosalpingography.

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