

נובמבר 2025

## Iomeron 300, 350, 400 mg, Solution for Injection

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים: איומרון 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 בנובמבר 2025. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

#### 4.4 Special warnings and precautions for use

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Diagnostic procedures which involve the use of any radiopaque medium should be carried out under the direction of personnel with the prerequisite training and with a thorough knowledge of the particular procedure to be performed.

Appropriate facilities should be available for coping with any complication of the procedure, as well as for emergency treatment of severe reactions, including hypersensitivity or anaphylactic reactions, to the contrast medium itself.

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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 severe functional impairment of the kidneys, liver or myocardium, myelomatosis or other paraproteinaemias, sickle cell disease, diabetes mellitus, polyuria, oliguria, hyperuricaemia, **neonates**, infants, elderly patients, **and patients with severe systemic disease** should not be exposed to dehydration. Caution should be exercised in hydrating patients with underlying conditions that may be worsened by fluid overload, including congestive heart failure.

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#### *Renal impairment*

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**Preventive measures include:**

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**postponing a new contrast agent examination until renal function returns to the same level as before the examination.**

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