

נובמבר 2023

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 בנובמבר 2023. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

4.4 Special warnings and precautions for use

[...]

Special population

[...]

Thyroid function and thyroid function tests

The small amount of free inorganic iodide that may be present in contrast media might have some effects on thyroid function. These effects appear more evident in patients with latent or overt hyperthyroidism or goitre. Hyperthyroidism or even thyroid storms have been reported following administration of iodinated contrast media.

Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been reported following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism. See also section on Paediatric population.

[...]

Contrast induced encephalopathy

Encephalopathy has been reported with the use of iomeprol (see section 4.8).

Contrast encephalopathy 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 of iomeprol, and generally resolves within days.

The product should be used with caution in patients with conditions that disrupt the integrity of the blood brain barrier (BBB), potentially leading to increased permeability of contrast media across the BBB and increasing the risk of encephalopathy. If contrast encephalopathy is suspected, administration of iomeprol should be discontinued and appropriate medical management should be initiated.

[...]

Severe cutaneous adverse reactions

Severe cutaneous reactions (SCARs) including Steven-Johnson (SJS), toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported in association with the intravascular administration of iodinated contrast agents (see Section 4.8). At the time of administration patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, Iomeron should be stopped immediately. If the patient has developed a serious reaction such as SJS, TEN, AGEP or DRESS with the use of Iomeron, administration of Iomeron must not be restarted to this patient at any time.

[...]

4.8 Undesirable Effects

[...]

4.8.1 Intravascular administration

Adults

System Organ Class	Adverse Reactions			
	Clinical Trials			Post-marketing Surveillance
	Common (≥1/100 to <1/10)	Uncommon (≥1/1000 to <1/100)	Rare (≥1/10,000 to <1/1000)	Frequency unknown*
				[...]
Endocrine disorders				Hyperthyroidism
				[...]
Nervous system disorders				Contrast induced encephalopathy***
				[...]
Vascular disorders				Coronary artery thrombosis Coronary artery embolism Vasospasm**** Ischemia****
				[...]
Skin and subcutaneous tissue disorders				Stevens-Johnson's syndrome Toxic epidermal necrolysis Erythema multiforme Drug Reaction with Eosinophilia and Systemic Symptoms

[...]

*** Encephalopathy 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, brain oedema.

[...]

****Transient renal failure with oliguria, proteinuria and an increase in serum creatinine may develop, particularly in patients with impaired renal function. In case of extravasal injection a tissue reaction may develop in rare cases.

[...]

Transient hypothyroidism may occur in neonates, especially in preterm or low birth weight neonates, and children (0-3 years), when exposed to iomeprol.

5.3 Preclinical safety data

Pre-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, toxicity to reproduction.

Results from studies in rats, mice and dogs demonstrate that iomeprol has an acute intravenous or intra-arterial toxicity similar to that of the other non-ionic contrast media, as well as a good systemic tolerability after repeated intravenous administrations in rats and dogs.