Iomeron®
Iomeprol

IOMEPROL, N, N'-bis(2,3-dihydroxypropyl)-5[(hydroxyacetyl)methylamino]-2,4,6-triiodo-1,3 benzenedicarboxamide, the active component of Iomeron, is a triiodinated, non-ionic, water soluble X ray contrast agent with a molecular weight of 777.09.

List of excipients
Trometamol
Hydrochloric Acid (pH adjustment)
Water for Injection

Clinical Pharmacology
The pharmacokinetics, tolerability and diagnostic efficacy of iomeprol in solutions containing up to 400 mg iodine/ml have been determined in healthy volunteers and patients requiring urographic, angiographic, computed tomography (CT) and body cavity examinations. There were no clinically significant changes in laboratory test values and vital signs.
The pharmacokinetics of iomeprol, following intravascular administration, when described by a two compartment model, show a rapid phase for drug distribution and a slower phase for drug elimination. In 18 healthy volunteers the mean half-lives of the distribution and elimination phases were 23 ± 14 (s) min and 109 ± 20 (s) min, respectively, with an excretion of 50% by the urinary tract within 2 hours after administration.

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

Dosage and Administration

Indication	**Formulation mg (iodine)/ml**	**Proposed dosages**
Intravenous urography	400	Adults: 50 – 150 ml Neonates: 3 – 4.8 ml/kg Babies: 2.5 – 4 ml/kg ≤ 1 year Children: 1 – 2.5 ml/kg > 1 year
CT body	400	Adults: 100-200 ml Children[a]
Intravenous DSA	400	Adults: 100-250 ml Children[a]
Conventional angiography Arteriography of pelvis and lower extremities Abdominal arteriography Pulmonary angiography Interventional arteriography	 400 400 400 400	 Adults[b] Adults[b] Adults: up to 170 ml Adults[b] Children[a]
Angiocardiography	400	Adults[b] Children: 3-5 ml/kg
Conventional selective	400	Adults: 4-10 ml per artery,

coronary arteriography		repeat if necessary
Fistulography	400	Adults: up to 100 ml
Galactography	400	Adults: 0.15 – 1.2 ml for injection
Dacryocystography	400	Adults: 2.5 – 8 ml for injection
Sialography	400	Adults: 1 – 3 ml for injection

a = According to body weight and age.
b = Do not exceed 250 ml. Single injection volume depends on the vascular area to be examined.

Contraindications
Hypersensitivity to the active substance or to any of the excipients listed above.

Precautions for use
In relation to the patient:
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 myelomatosis or other paraproteinaemias, sickle cell disease, diabetes mellitus, polyuria, oligouria, hyperuricaemia, neonates, infants and elderly patients 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.
Dietary suggestions. Unless otherwise instructed by the doctor, a normal diet may be maintained on the day of the examination. Adequate fluid intake must be ensured. However, for two hours prior to the procedure the patient should refrain from eating.
History of hypersensitivity. In patients with an allergic disposition, known hypersensitivity to iodinated contrast media and a history of asthma, premedication with antihistamines and/or corticoids may be considered in order to prevent possible anaphylactoid reactions.
Anxiety. Pronounced states of excitement, anxiety and pain can be the cause of side effects or intensify contrast-related reactions. These patients may be given a sedative.
Co-medication. Consider the discontinuation of treatment with drugs that lower the seizure threshold until 24 hours post-procedure for intrathecal use and patients with blood-brain barrier disorders (see CNS disorders). Anticonvulsant therapy must not be discontinued and should be administered in optimal dosage.
Mixing with other drugs. In order to avoid possible incompatibilities, contrast media must not be mixed with other drugs.
In relation to procedure:
Coagulation, flushing of catheters. A property of non-ionic contrast media is the low interference with normal physiological functions. As a consequence of this, non-ionic contrast media have less anticoagulant activity in vitro than ionic media. Medical personnel performing a vascular catheterization procedure should be aware of this and pay meticulous attention to angiographic technique. Non-ionic media should not be allowed to remain in contact with blood in the syringe and intravascular catheters should be flushed frequently to minimize the risk of clotting, which rarely has led to serious thromboembolic complications after procedures.
Observation of the patient. Intravascular administration of contrast media should, if possible, be done with the patient lying down. The patient should be kept under observation for at least 30 minutes after administration.
Pretesting. Sensitivity test doses are not recommended since severe or fatal reactions to contrast media are not predictable from a patient's history or a sensitivity test.

Special warnings - Common to all types of administration
In consideration of possible serious side effects, the use of organoiodinated contrast media should be limited to cases for which there is a precise need for contrastographic examination. The need should be evaluated on

the basis of the clinical status of the patient, in particular in relation to pathologies on the cardiovascular, urinary or hepatobiliary systems.
Contrast media designed for angiocardiographic procedures should be used in hospitals or clinics equipped and staffed for intensive care in emergencies. In institutions, where other more common diagnostic procedures calling for the use of iodinated contrast media are to take place, resuscitation equipment and therapeutic measures should be immediately available.

Use in:
Neonates, infants and children. Young infants (age < 1 year) especially neonates 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.

Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast agents in pediatric patients 0 years to 3 years of age.

Younger age, very low birth weight, prematurity, underlying medical conditions affecting thyroid function, admission to neonatal or pediatric intensive care units, and congenital cardiac conditions are associated with an increased risk of hypothyroidism after iodinated contrast agent exposure. Pediatric patients with congenital cardiac conditions may be at greatest risk given that they often require high doses of contrast during invasive cardiac procedures.

An underactive thyroid during early life may be harmful for cognitive and neurological development and may require thyroid hormone replacement therapy. After exposure to iodinated contrast agents, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates.

Pregnant women. Animal studies have not shown any teratogenicity or embryotoxicity after iomeprol administration. As with other non-ionic contrast media, there are no controlled studies in pregnant women to confirm the safety for use in humans too. Since, wherever possible, exposure to radiation should be avoided during pregnancy, the benefits of any X-ray examination, whether with or without contrast material, should for this reason alone be carefully weighed against the possible risk. In neonates who have been exposed to iomeprol in utero, it is recommended to monitor thyroid function.
Breastfeeding women. Contrast media are poorly excreted in human breast milk. From experience gained so far, harm to the nursing infant is unlikely to occur.
Elderly. The elderly are at special risk of reactions due to CM high dosage. The frequently encountered combination of neurological disturbances and severe vascular pathologies constitutes a serious complication.
Use in patients with specific pathological conditions:
Hypersensitivity to iodinated contrast media. Hypersensitivity or a previous history of a reaction to iodinated contrast media also increases the risk of recurrence of a severe reaction with non ionic contrast media.
Allergic disposition. It is generally agreed that adverse reactions to iodinated contrast media are more common in patients having a history of allergy: hay fever, hives and food allergy.
Asthmatic patients. Patients using beta-adrenergic blocking agents, particularly asthmatic patients, may have a lower threshold for bronchospasm and are less responsive to treatment with beta agonists and adrenaline, which may necessitate the use of higher doses of adrenaline.
The risk of bronchospasm-inducing reactions in asthmatic patients is higher after contrast media administration.
Hyperthyroidism, nodular goitre. The small amount of 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.

Effects on ability to drive or to operate machinery
No data are available but, since delayed reactions can rarely occur after administration of iodinated contrast media, driving or operating machinery is not advisable for the first 24 hours following contrast medium (CM) examination.
Renal failure. Preexisting renal impairment may predispose to acute renal dysfunction following contrast media administration. Preventive measures include: identification of high risk patients; ensuring adequate

hydration before CM administration, preferably by maintaining i.v. infusion before and during the procedure and until the CM has been cleared by the kidneys; avoiding, whenever possible, the administration of nephrotoxic drugs or major surgery or procedures such as renal angioplasty, until the CM has been cleared; postponing a new contrast agent examination until renal function returns to pre-examination levels. Patients on dialysis may receive CM, such as iomeprol, which may be cleared by dialysis.

Diabetes mellitus. The presence of renal damage in diabetic patients is one of the factors predisposing to renal impairment following CM administration. This may precipitate lactic acidosis in patients who are taking biguanides.–To prevent onset of lactic acidosis in diabetic patients under treatment with oral anti-diabetic agents of the biguanide class (Metformin), these agents should be stopped in the following scenarios; prior to an intraarterial contrast medium administration with first pass renal exposure, in patients with eGFR less than 30 ml/min/1.73m^2 receiving intravenous contrast medium, or intra-arterial contrast medium with second pass renal exposure, or in patients with acute kidney injury, and re-instated only after 48 hours if renal function has not changed significantly.

Multiple myeloma, paraproteinaemia. It is necessary to consider that the presence of myelomatosis or paraproteinaemias is a factor predisposing to renal impairment following CM administration. Adequate hydration is recommended. **The benefits of the use of a contrast-enhanced procedure should be carefully weighted against the possible risk**.

Phaeochromocytoma. These patients may develop severe (rarely uncontrollable) hypertensive crises following intravascular CM-usage during radiological procedures. Premedication with alpha and beta-receptor blockers is recommended before intra-arterial injection of contrast media under the supervision of a physician because of the risk of blood pressure crises.

Severe cardiovascular disease. There is an increased risk of severe reactions in individuals with severe cardiac disease and particularly in those with heart failure and coronary artery disease. The intravascular CM injection may precipitate pulmonary oedema in patients with manifest or incipient heart failure, whereas CM administration in pulmonary hypertension and heart valvular diseases, may lead to pronounced haemodynamic changes. Ischaemic ECG changes and major arrhythmias are commonest in elderly patients and in those with preexisting cardiac disease: their frequency and severity appear to be related to the severity of cardiac impairment. Severe and chronic hypertension may increase the risk of renal damage following CM administration and the risks associated with the catheterisation procedure.

CNS disorder. Particular care should be paid to the intravascular administration of CM in patients with acute cerebral infarction, acute intracranial haemorrhage, and conditions involving blood-brain-barrier (BBB) damage, brain oedema and acute demyelination.

The presence of intracranial tumors or metastases and a history of epilepsy may increase the probability of the occurrence of convulsive seizures.

Neurological symptoms due to degenerative, ischaemic, recent stroke or frequent TIA (transient ischaemic attack), inflammatory or neoplastic cerebrovascular pathologies may be exacerbated by CM administration. These patients have an increased risk of transient neurological complications.

Vasospasm and consequent cerebral ischaemic phenomena may be caused by intravascular injections of CM.

Contrast induced encephalopathy

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

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.

Alcoholism. Acute and chronic alcoholism have been proven both experimentally and clinically to increase BBB permeability. This facilitates the passage of iodinated agents into the cerebral tissue, possibly leading to CNS disorders. Caution must be exercised in alcoholics because of the possibility of a reduced seizure threshold.

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.
Drug addiction. Caution must be exercised in drug addicts because of the possibility of a reduced seizure threshold.

Interactions
Thyroid function tests. Following administration of iodinated contrast media, the capacity of the thyroid tissue to take up radioisotopes for the diagnosis of thyroid disorders is reduced for up to two weeks, or even longer in individual cases.
Laboratory tests. High concentrations of contrast media in serum and urine can interfere with laboratory test results of bilirubin, proteins or inorganic substances (e.g. iron, copper, calcium, phosphate).

Overdosage
Overdosage may lead to life-threatening adverse effects mainly through effects on the pulmonary and cardiovascular system. Treatment of overdosage is directed toward the support of all vital functions and prompt institution of symptomatic therapy. Iomeprol does not bind to plasma or serum proteins and is therefore dialyzable. LD50 values (g iodine/kg) for iomeprol and the respective 95% confidence limits in animals are:

intravenous:	19,9 (19,3 – 20,5) (mouse)	14,5 (13,2 – 16,0) (rat)	> 12,5 (dog)
intraperitoneal:	26,1 (23,3 – 29,2) (mouse)	10 (8,9 – 11,3) (rat)	
intracerebral:	1,3 (1,2 – 1,5) (mouse)		
intracisternal:	> 1,2 (rat)		
intracarotid:	5,8 (4,64 – 7,25) (rat)		

Undesirable effects
Side effects are usually mild to moderate and transient in nature. However, severe and life-threatening reactions sometimes leading to death have been reported. In most cases, reactions occur within minutes of dosing but at times reactions may occur at later time.
Anaphylaxis (anaphylactoid/hypersensitivity reactions) may manifest with various symptoms, and rarely does any one patient develop all the symptoms. Typically, in 1 to 15 min (but rarely after as long as 2 h), the patient complains of feeling abnormal, agitation, flushing, feeling hot, sweating increased, dizziness, lacrimation increased, rhinitis, palpitations, paraesthesia, pruritus, head throbbing, pharyngolaryngeal pain and throat tightness, dysphagia, cough, sneezing, urticaria, erythema, and mild localised oedema or angioedema and dyspnoea owing to tongue and laryngeal oedema and/or laryngospasm manifesting with wheezing and bronchospasm.
Nausea, vomiting, abdominal pain, and diarrhoea are also reported.
These reactions, which can occur independently of the dose administered or the route of administration, may represent the first signs of circulatory collapse.
Administration of the contrast medium must be discontinued immediately and, if needed, appropriate specific treatment urgently initiated via venous access.
Severe reactions involving the cardiovascular system, such as vasodilatation, with pronounced hypotension, tachycardia, 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.
The adverse reactions reported in clinical trials among 4,920 adult patients and from post-marketing surveillance are represented in the tables below by frequency and classified by MedDRA system organ class. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.
Adult patients involved in clinical trials with **intravascular administration** of iomeprol were 4,739.

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***
Blood and lymphatic system disorders				Thrombocytopenia, Haemolytic anaemia
Immune system disorders				Anaphylactoid reaction
Endocrine disorders				Hyperthyroidism
Psychiatric disorders				Anxiety, Confusional state
Nervous system disorders		Dizziness, Headache	Presyncope	Coma, Transient ischaemic attack, Paralysis, Syncope, Convulsion, Loss of consciousness, Dysarthria, Paraesthesia, Amnesia, Somnolence, Taste abnormality, Contrast induced encephalopathy***
Eye disorders				Blindness transient, Visual disturbance, Conjunctivitis, Lacrimation increased, Photopsia
Cardiac disorders			Bradycardia, Tachycardia, Extrasystoles	Cardiac arrest, Myocardial infarction, Cardiac failure, Angina pectoris, Arrhythmia, Ventricular or atrial fibrillation, Atrioventricular block
Vascular disorders		Hypertension	Hypotension	Circulatory collapse or shock, Flushing, Pallor, Cyanosis, Coronary artery thrombosis. Coronary artery embolism, Vasospasm****, Ischemia****
Respiratory, thoracic and mediastinal disorders		Dyspnoea		Respiratory arrest, Acute respiratory distress syndrome (ARDS), Pulmonary oedema, Laryngeal oedema, Pharyngeal oedema, Bronchospasm, Asthma, Cough, Pharynx discomfort, Laryngeal discomfort, Rhinitis, Dysphonia
Gastrointestinal disorders		Vomiting, Nausea		Diarrhoea, Abdominal pain, Salivary hypersecretion, Dysphagia,

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*
				Salivary gland enlargement
Skin and subcutaneous tissue disorders		Erythema, Urticaria, Pruritus	Rash	Acute generalized exanthematous pustulosis, Angioedema, Sweating increased, Stevens-Johnson's syndrome, Toxic epidermal necrolysis, Erythema multiforme, Drug Reaction with Eosinophilia and Systemic Symptoms
Musculoskeletal and connective tissue disorder			Back pain	Arthralgia
Renal and urinary disorders				Acute kidney injury*****
General disorders and administration site conditions	Feeling hot	Chest pain, Injection site warmth and pain	Asthenia, Rigors, Pyrexia	Injection site reaction**, Coldness local, Malaise, Thirst
Investigations			Blood creatinine increased	Electrocardiogram ST segment elevation, Electrocardiogram abnormal

* Since the reactions were not observed during clinical trials with 4739 patients, best estimate is that their relative occurrence is rare (≥1/10,000 to <1/1000).
The most appropriate MedDRA term is used to describe a certain reaction and its symptoms and related conditions.
** Injection site reactions comprise injection site pain and swelling. In the majority of cases they are due to extravasation of contrast medium. These reactions are usually transient and result in recovery without sequelae. Cases of extravasation with inflammation, skin necrosis and even development of compartment syndrome have been reported.
*** 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.
**** Vasospasm and consequent ischaemia have been observed during intra-arterial injections of contrast medium, in particular after coronary and cerebral angiography often procedurally related and possibly triggered by the tip of the catheter or excess catheter pressure.
***** 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.

Paediatric patients
There is limited experience with paediatric patients. The clinical trial paediatric safety database comprises 184 patients.
The iomeprol safety profile is similar in children and adults.
Transient hypothyroidism may occur in neonates when exposed to iomeprol, especially in preterm or low birth weight neonates, and children (0-3 years), when exposed to iomeprol.

Reporting of suspected adverse reactions.
Reporting suspected adverse reactions after authorisation of the medical product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professional are asked to report any suspected adverse reactions to Pusat Farmakovigilans/MESO Nasional or email to pharmacovigilance@dipa.co.id.

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 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.

Storage
Keep away from light. The bottle, once opened, has to be used immediately. Any residue of contrast medium must be discarded.
Store at 25°C.

Single use
Vials containing contrast media solution are not intended for the withdrawal of multiple doses. The rubber stopper should never be pierced more than once. The use of proper withdrawal cannulas for piercing the stopper and drawing up the contrast medium is recommended. The contrast medium should not be drawn into the syringe until immediately before use. Solutions not used in one examination session must be discarded.

Packaging
Iomeron 400: - Bottle of 50ml Reg. No.: DKI2010400243A1
- Bottle of 100ml Reg. No.: DKI2010400243A1

HARUS DENGAN RESEP DOKTER

Manufactured and Released by:
Patheon Italia S.p.A., Ferentino - Italy
For Bracco Suisse SA, Cadempino - Switzerland

Imported by:
PT. Dipa Pharmalab Intersains
Majalengka – Indonesia

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LEAFLET INFORMASI PASIEN: INFORMASI UNTUK PENGGUNA

Iomeron 400

Larutan injeksi Iomeprol

Bacalah leaflet ini dengan seksama sebelum Anda memulai pengobatan dengan obat ini karena mengandung informasi penting untuk Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter Anda.
- Obat ini diresepkan hanya untuk Anda. Jangan memberikannya kepada orang lain. Obat ini dapat membahayakan mereka, meskipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika terdapat efek samping, konsultasikan kepada dokter Anda. Hal ini termasuk kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 4.

Leaflet ini berisi:

1. Kandungan dan kegunaan Iomeron

Iomeron mengandung iomeprol, bahan aktif yang termasuk dalam kelompok produk obat yang disebut media kontras. Produk ini dimaksudkan untuk penggunaan diagnostik, selama pemeriksaan radiologi. Produk ini menyerap sinar X, membantu dokter Anda melihat pembuluh darah dan struktur internal tubuh dengan lebih baik untuk diselidiki dengan sinar X.

2. Hal yang perlu Anda ketahui sebelum menggunakan Iomeron

Anda tidak boleh diberikan Iomeron jika Anda alergi terhadap iomeprol atau bahan lain dari Iomeron (lihat daftar bahan di Bagian 6).

Peringatan dan perhatian

Bicarakan dengan dokter, perawat atau apoteker Anda sebelum diberikan Iomeron jika Anda memiliki salah satu kondisi berikut:
- alergi terhadap media kontras golongan iodium
- memiliki kecenderungan untuk alergi (memiliki riwayat alergi)
- pasien asma
- kadar hormon tiroid terlalu tinggi di dalam tubuh/gondok
- ganguan ginjal
- diabetes mellitus
- multiple myeloma (tumor sel darah putih)
- paraproteinemia (protein abnormal dalam darah)
- gangguan jantung
- rutin mengonsumsi alkohol
- penyakit kulit
- kecanduan narkoba

Beritahu dokter Anda jika Anda ingin menjalani tes fungsi tiroid, karena iomeprol dapat mengganggu tes ini.

Selama atau segera setelah prosedur pencitraan, Anda mungkin mengalami gangguan otak jangka pendek yang disebut ensefalopati. Beritahu dokter Anda segera jika Anda melihat salah satu gejala yang berhubungan dengan kondisi yang dijelaskan di Bagian 4.

Gangguan tiroid dapat diamati pada anak dan dewasa setelah pemberian Iomeron. Dokter Anda perlu melakukan tes fungsi tiroid sebelum dan/atau setelah pemberian Iomeron.

Perhatian pada saat penggunaan Iomeron:

Telah dilaporkan terjadi reaksi kulit serius termasuk sindrom Stevens-Johnson (SJS), nekrolisis epidermal toksik (NET), pustulosis eksantema generalisata akut (PEGA), dan reaksi obat dengan eosinofilia dan gejala sistemik (DRESS) terkait penggunaan Iomeron. Segera hubungi petugas medis jika Anda mengalami salah satu gejala yang terkait dengan reaksi kulit serius yang dijelaskan di Bagian 4.

Pada semua pasien dehidrasi harus dihindari dan mungkin perlu diberikan cairan untuk memastikan hal ini. Perhatian khusus harus diberikan pada anak-anak dan orang lanjut usia, dan pada pasien dengan penyakit penyerta seperti gangguan hati, jantung atau ginjal, diabetes, dan mereka yang sangat rentan terhadap dehidrasi.

Obat-obatan lain dan Iomeron

Beritahu dokter, perawat, atau apoteker Anda jika Anda sedang mengonsumsi, baru saja mengonsumsi, atau mungkin mengonsumsi obat lain, termasuk obat yang diperoleh tanpa resep. Beritahu dokter Anda jika Anda sedang mengonsumsi obat-obatan berikut, karena obat-obatan tersebut dapat bereaksi dengan Iomeron:

- obat diabetes, biguanida (misalnya metformin).
- anti-epilepsi (pengobatan serangan epilepsi)
- obat penyakit jiwa
- agen vasopresor (digunakan untuk meningkatkan tekanan darah)
- beta blocker (pengobatan untuk masalah detak jantung)

Mungkin Anda tetap boleh diberikan Iomeron dan dokter Anda akan dapat memutuskan mana yang cocok untuk Anda.

Iomeron dengan makanan dan minuman

Kecuali diinstruksikan lain oleh dokter, Anda harus menjaga pola makan normal pada hari pemeriksaan.

Kehamilan, menyusui, dan kesuburan

Jika Anda sedang hamil atau menyusui, Anda hanya boleh diberikan Iomeron jika menurut dokter Anda memang membutuhkannya. Beritahu dokter Anda jika Anda sedang hamil atau menyusui atau ada kemungkinan Anda sedang hamil atau berencana untuk memiliki bayi. Jika Anda sedang hamil, dan telah menerima Iomeron selama kehamilan, disarankan untuk memantau fungsi tiroid bayi Anda setelah lahir.

Mintalah nasihat dokter, perawat atau apoteker Anda sebelum minum obat apa pun.

Mengemudi dan menggunakan mesin

Tidak diketahui efek Iomeron pada kemampuan mengemudi atau mengoperasikan mesin, namun Anda tidak boleh mengemudi atau mengoperasikan mesin selama 24 jam setelah penyuntikan karena kemungkinan adanya reaksi.

3. Cara penggunaan Iomeron

Iomeron akan diberikan kepada Anda oleh dokter atau perawat di rumah sakit atau klinik. Iomeron akan disuntikkan ke dalam pembuluh darah arteri atau vena atau ke dalam rongga tubuh.

Dosis
Dosis yang dianjurkan tergantung pada bagian tubuh mana yang dirontgen dan biasanya berkisar antara 0,15 ml – 250 ml. Dokter Anda mungkin memutuskan untuk memvariasikan dosis ini atau mengulangi dosis jika diperlukan.
Dosis untuk anak-anak juga tergantung pada usia dan ukuran tubuh.

Jika Anda memiliki pertanyaan lebih lanjut mengenai penggunaan produk ini, tanyakan kepada dokter, perawat atau apoteker Anda.

Jika Anda diberi lebih banyak Iomeron dari yang seharusnya:
Anda harus tahu bahwa area rumah sakit atau klinik tempat Iomeron diberikan kepada Anda dilengkapi dengan baik untuk menangani segala efek dari overdosis.

4. Kemungkinan efek samping

Seperti semua obat-obatan, Iomeron dapat menyebabkan efek samping, meski tidak semua orang mengalaminya. Biasanya ringan sampai sedang dan tidak berkepanjangan. Namun, reaksi parah dan mengancam jiwa terkadang menyebabkan kematian telah dilaporkan. Setelah pemberian melalui suntikan ke pembuluh darah atau arteri, sebagian besar reaksi terjadi dalam beberapa menit, dan setelah injeksi ke dalam rongga tubuh atau tulang belakang, sebagian besar reaksi terjadi dalam beberapa jam atau lebih.

Beritahu dokter Anda segera jika Anda tiba-tiba mengalami mengi, kesulitan bernapas, pembengkakan pada kelopak mata, wajah atau bibir, ruam atau gatal-gatal (terutama mempengaruhi seluruh tubuh Anda).

Efek samping berikut telah dilaporkan:

Umum (antara 1 dari 10 dan 1 dari 100 pasien)
- merasa panas

Jarang (antara 1 dari 100 dan 1 dari 1000 pasien)
- sakit kepala
- pusing
- peningkatan tekanan darah
- sesak napas
- muntah
- mual
- kemerahan
- pembengkakan pada kulit
- gatal
- nyeri dada
- rasa hangat dan nyeri di tempat penyuntikan

Sangat Jarang (antara 1 dari 1000 dan 1 dari 10.000 pasien)

- detak jantung lambat atau cepat, detak jantung tidak teratur
- penurunan tekanan darah
- ruam
- sakit punggung

- kelemahan parah
- demam
- perubahan pada beberapa tes darah (kreatinin)

Tidak diketahui: (tidak dapat diperkirakan)

- segera hubungi dokter jika mengalami reaksi kulit yang serius seperti:
  - lepuh/ benjolan kecil berisi cairan pada permukaan kulit, kulit mengelupas, sariawan pada mulut, tenggorokan, hidung, alat kelamin dan mata. Ruam kulit yang serius ini dapat diawali dengan demam dan gejala mirip flu (sindrom *Stevens-Johnson*, nekrolisis epidermal toksik/reaksi kulit yang sangat berat dan langka/jarang).
  - ruam merah bersisik disertai benjolan di bawah kulit dan melepuh disertai demam. Gejala biasanya muncul pada awal pengobatan (pustulosis eksantematosa generalisata akut/ reaksi kulit akut yang berat ditandai dengan munculnya banyak benjolan kecil berisi nanah di atas kulit yang memerah dan meradang, menyebar ke seluruh tubuh)
  - ruam yang meluas, suhu tubuh tinggi dan pembengkakan kelenjar getah bening (sindrom DRESS atau sindrom hipersensitivitas obat).
- memar atau pendarahan tanpa sebab yang jelas (akibat rendahnya kadar trombosit)
- anemia hemolitik (pemecahan sel darah merah secara tidak normal, yang dapat menyebabkan kelelahan, detak jantung cepat, dan sesak napas)
- reaksi alergi berat
- hipertirod
- kecemasan, kebingungan
- koma, stroke ringan, aliran darah ke otak terbatas atau tidak ada sama sekali, lumpuh, kejang, kehilangan kesadaran atau pingsan
- gangguan otak (ensefalopati) dengan gejala termasuk sakit kepala, kesulitan penglihatan, kehilangan penglihatan, kebingungan, kejang, kehilangan koordinasi, kehilangan gerakan pada satu sisi tubuh, kesulitan berbicara, dan kehilangan kesadaran
- kesulitan berbicara
- sensasi kulit yang tidak normal (seperti kesemutan atau geli)
- gangguan ingatan
- keinginan kuat untuk tidur
- perubahan rasa
- gangguan penglihatan, termasuk kebutaan sementara
- iritasi mata, peningkatan air mata
- henti jantung, serangan jantung, gagal jantung, irama jantung tidak normal
- syok, kemerahan akibat pembesaran pembuluh darah, kulit pucat (pucat), perubahan warna kulit dan selaput lendir menjadi biru, bekuan darah, penyempitan pembuluh darah dan “berakhir pada iskemia (kerusakan pembuluh darah)”
- pernafasan terhenti, kesulitan bernafas, paru-paru berair, kotak suara bengkak, asma, batuk pilek, rasa tidak nyaman di tenggorokan, hidung tersumbat
- diare, sakit perut, peningkatan air liur, pembesaran kelenjar ludah, kesulitan menelan
- pembengkakan pada kulit, peningkatan keringat, Sindrom Stevens-Johnson, nekrolisis epidermal toksik, eritema multiforme, reaksi obat dengan Eosinofilia dan gejala sistemik
- nyeri sendi
- gagal ginjal akut
- bengkak di tempat suntikan
- merasa kedinginan
- perasaan tidak nyaman atau tidak nyaman
- haus
- elektrokardiogram abnormal
- nyeri panggul

Gangguan hipotiroid sementara dapat terjadi pada anak di bawah usia 3 tahun.

Pelaporan efek samping
Jika Anda mendapatkan efek samping apa pun, bicarakan dengan dokter Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam brosur ini. Anda juga dapat melaporkan efek samping secara langsung melalui *pharmacovigilance@dipa.co.id*

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.
Jika Anda mempunyai pertanyaan lain yang belum terjawab dalam brosur ini, silakan tanyakan kepada staf medis.

5. Cara penyimpanan Iomeron

Anda tidak perlu menyimpan obat sendiri. Dokter, perawat atau apoteker rumah sakit Anda akan mengetahui cara menyimpan Iomeron.
Jauhkan obat ini dari pandangan dan jangkauan anak-anak. Simpan pada suhu 25°C. Simpan dalam wadah aslinya.
Jangan gunakan obat ini setelah tanggal kedaluwarsa yang tertera pada label. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.
Iomeron harus segera diberikan kepada Anda setelah dimasukkan ke dalam *syringe*.
Botol dimaksudkan untuk sekali pakai saja; bagian yang tidak terpakai harus dibuang.
Setelah dibuka: Larutan yang tidak digunakan pada satu sesi pemeriksaan harus dibuang.
Jangan membuang obat apa pun melalui air limbah atau limbah rumah tangga. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi dalam kemasan dan informasi lainnya

Kandungan Iomeron
Satu ml Iomeron 400 mengandung 81,65% zat aktif iomeprol yang setara dengan 400 mg yodium. Bahan lainnya adalah trometamol, asam klorida dan air untuk injeksi.

Bentuk Iomeron dan isi kemasannya
Iomeron tersedia dalam botol kaca berisi: 50 dan 100 ml larutan bening tidak berwarna.

HARUS DENGAN RESEP DOKTER

Kemasan dan Nomor Izin Edar
Iomeron 400 @50 ml, No. Reg: DKI2010400243A1
Iomeron 400 @100 ml, No. Reg: DKI2010400243A1

Diproduksi oleh:
Patheon Italia S.p.A., Ferentino - Italy
untuk
Bracco Suisse SA, Cadempino - Switzerland

DIPA HEALTHCARE

Diimpor oleh:
PT Dipa Pharmalab Intersains
Majalengka – Indonesia

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