20 DIC 2024
CROMinFOTO s.n.c.
GRAFICA - FOTOCOMPOSIZIONE
Via G. Tartini, 2 - 20158 - MILANO
AZIENDA CERTIFICATA UNI EN ISO 9001:2015

*CI00O8-07 solo per registrazione

FCI00O8-08 PIL IOME
Versione interna: 01

Impianto di proprietà della: BRACCO — Bracco s.p.a. via E. Folli, 50 - 20134 Milano - Italy
patheon by Thermo Fisher Scientific — Patheon Italia S.p.A. viale G.B. Stucchi, 110 - 20900 Monza (MB) - Italy — Cliente: BRACCO s.p.a.
Prodotto: IOMERON (MALESIA)

SPECIFICA RIFERIMENTO: SF 0005 IS+P	Materiale: Istruzione	Codice Patheon: 000000	Codice Patheon superato: 252114	Codice Bracco: CI00O8-08	Codice Bracco superato: CI00O8-06 (CI00O8-07)*

Dimensioni: 150x700 mm — Stesa ☒ Piegata ☒ Bobina ☐ Pre taglio ☐ Passo di taglio a mm — CODICE LAETUS — Apri nota digitale se presente

Colori n°:	Black					
01						

Modifica rispetto la versione precedente: ADDITION OF ADMINISTRATION TO BODY CAVITIES

Packaging Development	Data Emissione	Data Obsolescenza	Status

I colori su questa prova sono approssimativi, questa è una stampa a 600 dpi ottenuta con colori a base acqua CMYK. Definizione e colori non riflettono il risultato finale della produzione stampata.

FRONTE - Font size heading c. 19 - Font size subheading c. 00 - Font size main text c. 8 - Font size line-spacing 8.3

Iomeron®

BRACCO

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, formulations of which yield contrast media of particularly low osmolality and viscosity in comparison with other non-ionic media.
Iomeprol has been formulated in a wide range of concentrations (up to 400 mg iodine/ml). All have proved to be extremely stable both to heat sterilization and prolonged room temperature storage, without the chelator (EDTA salt) required by other contrast agents. The physico-chemical characteristics of injectable solutions of Iomeron at the concentrations listed below are:

Iodine Concentration *mg/ml*	**Osmolality*** *mosmol/kg water* ($x \pm s \bullet t_{95}$)	**Viscosity** *mPa.s* ($x \pm s \bullet t_{95}$)	
	37° C	**20° C**	**37° C**
350	618 ± 29	14.5 ± 1.1	7.5 ± 0.6
400	726 ± 34	27.5 ± 2.3	12.6 ± 1.1

* By vapour-pressure osmometry

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

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

Instructions for use

Indication	**Formulation** mg (iodine)/ml	**Proposed dosages**	
Intravenous urography	350, 400	Adults: Neonates: Babies: Children:	50 - 150 ml 3 - 4.8 ml/kg 2.5 - 4 ml/kg ≤ 1 year 1 - 2.5 ml/kg > 1 year
CT body	350, 400	Adults: Children[a]	100-200 ml
Intravenous DSA	350, 400	Adults: Children[a]	100-250 ml
Conventional angiography			
Arteriography of upper extremities	350	Adults[b]	
Arteriography of pelvis and lower extremities	350, 400	Adults[b]	
Abdominal arteriography	350, 400	Adults[b]	
Arteriography of descending aorta	350	Adults[b]	
Pulmonary angiography	350, 400	Adults:	up to 170 ml
Cerebral angiography	350	Adults:	up to 100 ml
Interventional arteriography	350, 400	Adults[b] Children[a]	
Intraarterial DSA			
Cerebral	350	Adults: Children[a]	30 - 60 ml for general view; 5 - 10 ml for selective angiography
Aortic arch	350	Adults[c]	
Aortography	350	Adults[c]	
Angiocardiography	350 ,400	Adults[b] Children:	 3-5 ml/kg
Conventional selective coronary arteriography	350, 400	Adults:	4-10 ml per artery, repeat if necessary
Arthrography	350	Adults:	up to 10 ml per injection
Hysterosalpingography	350	Adults:	up to 35 ml
Fistulography	350, 400	Adults:	up to 100 ml
Galactography	350, 400	Adults:	0.15 - 1.2 ml for injection
Dacryocystography	350, 400	Adults:	2.5 - 8 ml for injection
Sialography	350, 400	Adults:	1 - 3 ml for injection
Retrograde cholangiography	350	Adults:	up to 60 ml

[a] = According to body weight and age.
[b] = Do not exceed 250 ml. Single injection volume depends on the vascular area to be examined.
[c] = Do not exceed 350 ml.

Contraindications
Iomeprol Injection should not be administered to patients with known hypersensitivity to iomeprol or any of the excipients listed above.
Investigations of the female genitalia are contraindicated in suspected or confirmed pregnancy and in cases of acute inflammation.

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 severe functional impairment of the kidneys, liver or myocardium, myelomatosis or other paraproteinaemias, sickle cell disease, diabetes mellitus, polyuria, oligouria, 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.
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.

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).
Oral cholecystographics. Literature search has revealed no evidence of interactions of renally excreted contrast media with oral cholecystographic contrast media.

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.
Hypothyroidism or transient thyroid suppression may be observed after exposure to iodinated contrast media. Special attention should be paid to paediatric patients below 3 years of age because an incident underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient T4 replacement therapy. The incidence of hypothyroidism in patients younger than 3 years of age exposed to iodinated contrast media has been reported between 1.3% and 15% depending on the age of the subjects and the dose of the iodinated contrast agent and is more commonly observed in neonates and premature infants. Thyroid function should be evaluated in all paediatric patients younger than 3 years of age following exposure to iodinated contrast media. If hypothyroidism is detected, the need for treatment should be considered and thyroid function should be monitored until normalized.
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.
Hyperthyroidism, nodular goitre. 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.
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 risk factors pre-disposing to renal impairment following contrast media 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

20 DIC 2024
CROMinFOTO s.n.c.
GRAFICA - FOTOCOMPOSIZIONE
Via G. Tartini, 2 - 20158 - MILANO
AZIENDA CERTIFICATA UNI EN ISO 9001:2015

*CI00O8-07 solo per registrazione

FCI00O8-08 PIL IOME
Versione interna: 01

Impianto di proprietà della: BRACCO — Bracco s.p.a. via E. Folli, 50 - 20134 Milano - Italy

patheon by Thermo Fisher Scientific — Patheon Italia S.p.A. viale G.B. Stucchi, 110 - 20900 Monza (MB) - Italy

Cliente: BRACCO s.p.a.

Prodotto: IOMERON (MALESIA)

SPECIFICA RIFERIMENTO: SF 0005 IS+P	Materiale: Istruzione	Codice Patheon: 000000	Codice Patheon superato: 252114	Codice Bracco: CI00O8-08	Codice Bracco superato: CI00O8-06 (CI00O8-07)*

Dimensioni: 150 x 700 mm — Stesa ☒ Piegata ☒ Bobina ☐ Pre taglio ☐ Passo di taglio a mm

CODICE LAETUS

Apri nota digitale se presente

Colori n°:	Black					
01						

Modifica rispetto la versione precedente: ADDITION OF ADMINISTRATION TO BODY CAVITIES

Packaging Development	Data Emissione	Data Obsolescenza	Status

I colori su questa prova sono approssimativi, questa è una stampa a 600 dpi ottenuta con colori a base acqua CMYK. Definizione e colori non riflettono il risultato finale della produzione stampata.

RETRO - Font size heading c. 19 - Font size subheading c. 00 - Font size main text c. 8 - Font size line-spacing 8.3

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.

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.

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, 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.

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.

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. LD_{50} 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)		

Effects on ability to drive or to operate machinery

There is no known effect on the ability to drive a car or operate machines.

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, 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 4,739 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.

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

Store below 30°C. Protect from light.

Although the sensitivity of iomeprol to X-rays is low, it is advisable to store the product out of reach of ionizing radiation.

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.

How supplied

Iomeron 350 50 ml bottle. Presentation: Clear, colourless aqueous solution.
Iomeron 350 100 ml bottle. Presentation: Clear, colourless aqueous solution.
Iomeron 400 50 ml bottle. Presentation: Clear, colourless aqueous solution.
Iomeron 400 100 ml bottle. Presentation: Clear, colourless aqueous solution

Intraarterial and intravenous administration

DO NOT USE BEYOND EXPIRY DATE STATED ON THE LABEL.

Manufactured for Bracco Suisse S.A., Via Ponteggia 23, 6814 Cadempino, Switzerland
by Patheon Italia S.p.A., 2° Trav. SX Via Morolense 5 - 03013 Ferentino (FR), Italy

DATE OF REVISION: December 2024