Information for Healthcare Professionals Iomeron
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Change: Post-marketing update

Iomeron®

Composition

Active substance: Iomeprol

Excipients: Trometamol, hydrochloric acid, water for injection

Pharmaceutical form and amount of active substance per unit

Solution for injection

1 ml solution contains:

Iomeron	250 mg/ml	300 mg/ml	350 mg/ml	400 mg/ml
Iomeprol	510.3 mg	612.4 mg	714.4 mg	816.5 mg
Iodine content	250 mg/ml	300 mg/ml	350 mg/ml	400 mg/ml

Indications/possible uses

Adults

- Intravenous urography.
- Peripheral venography.
- CT (cranial and full-body).
- Cavernosography.
- Intravenous and intra-arterial DSA.
- Conventional angiography, angiocardiography.
- Arteriography of the upper and lower extremities, of the pelvis, abdominal arteriography, arteriography of the descending aorta, pulmonary arteriography, cerebral angiography, interventional arteriography, conventional selective coronary arteriography, interventional coronary arteriography.
- Hysterosalpingography; galactography.
- ERCP, endoscopic retrograde cholangio-pancreatography, cholangiography.
- Arteriography.
- Retrograde urethrography, retrograde ureteropyelography.

- Fistulography.
- Discography, dacryocystography, sialography, myelography.

Children

- Intravenous urography.
- CT (cranial and full-body).
- Intravenous and intra-arterial DSA.
- Interventional arteriography.
- Paediatric angiography.
- Angiocardiography.

Infants, neonates

- Intravenous urography.

CT: Computed tomography

DSA: Digital subtraction angiography

ERCP: Endoscopic retrograde cholangio-pancreatography

Dosage/administration

Indication	Dose strength Iodine mg/ml	Recommended dosage
Intravenous urography	250, 300, 350, 400	Adults: 50-150 ml Neonates: 3-4.8 ml/kg Infants: 2.5-4 ml/kg <1 year Children: 1-2.5 ml/kg >1 year
Peripheral venography	250, 300	Adults: 10-100 ml; the dose may be repeated as necessary. Do not exceed a dose of 250 ml. The injection dose depends on the part of the body being examined. (10-50 ml for the upper extremities;

		50-100 ml for the lower extremities)
Cranial CT	250, 300	Adults: 50-200 ml Children: according to body weight and age
Full-body CT	250, 300, 350, 400	Adults: 50-200 ml Children: according to body weight and age
Cavernosography	300	Adults: Up to 100 ml
Intravenous DSA	250, 300, 350	Adults: 100-250 ml Children: according to body weight and age
Conventional angiography		
Arteriography of the upper extremities	300, 350	Adults: Do not exceed a dose of 250 ml The injection dose depends on the part of the body being examined.
Arteriography of the lower extremities and of the pelvis	300, 350, 400	Adults: Do not exceed a dose of 250 ml The injection dose depends on the part of the body being examined.
Abdominal arteriography	300, 350, 400	Adults: Do not exceed a dose of 250 ml The injection dose depends on the part of the body being examined.
Arteriography of the descending aorta	300, 350	Adults: Do not exceed a dose of 250 ml The injection dose depends on the part of the body being examined.
Pulmonary angiography	300, 350, 400	Adults: Up to 170 ml
Cerebral angiography	300, 350	Adults: Up to 100 ml
Paediatric angiography	300	Up to 130 ml according to body weight and age

Abdominal arteriography	300, 350, 400	Adults: Do not exceed a dose of 250 ml The injection dose depends on the part of the body being examined. Children: according to body weight and age
Intra-arterial DSA		
Cerebral	300, 350	Adults: 30-60 ml for a general view; 5-10 ml for selective injection Children: according to body weight and age
Thoracic	300	Adults: 20-25 ml (aorta), to be repeated as necessary; 20 ml (bronchial arteries); do not exceed a dose of 250 ml. The injection dose depends on the part of the body being examined.
Aortic arch	300, 350	Adults: Do not exceed a dose of 350 ml
Abdomen	250, 300	Adults: Do not exceed a dose of 350 ml
Aortography	300, 350	Adults: Do not exceed a dose of 350 ml
Translumbar aortography	300	Adults: Do not exceed a dose of 250 ml. The injection dose depends on the part of the body being examined.
Peripheral arteriography	250, 300	Adults: 5-10 ml for selective injection, up to 250 ml Children: according to body weight and age
Interventional	300	Adults: 10-30 ml for selective injection, up to 250 ml Children: according to body weight and age
Angiocardiography.	300, 350, 400	Adults: Do not exceed a dose of 250 ml

		The injection dose depends on the part of the body being examined. Children: 3-5 ml/kg
Conventional selective coronary arteriography	300, 350, 400	Adults: 4-10 ml per artery, to be repeated as necessary
ERCP	300	Adults: up to 100 ml
Arthrography	300, 350	Adults: up to 10 ml per injection
Hysterosalpingography	300, 350	Adults: up to 35 ml
Fistulography	300, 350, 400	Adults: up to 100 ml
Discography	300	Adults: up to 4 ml
Galactography	300, 350, 400	Adults: 0.15-1.2 ml per injection
Dacryocystography	300, 350, 400	Adults: 2.5-8 ml per injection
Sialography	300, 350, 400	Adults: 1-3 ml per injection
Retrograde cholangio-pancreatography	300, 350	Adults: up to 60 ml
Retrograde urethrography	300	Adults: 20-100 ml
Retrograde ureteropyelography	300	Adults: 10-20 ml
Myelography	250 300	Adults: 10-18 ml per injection Adults: 8-15 ml per injection

Higher concentrations of Iomeron (350 and 400 mg/mL) are not recommended for intrathecal administration.

Iomeron can be given by intravenous or intra-arterial injection. The injection volume and the number of injections depend on the clinical and radiological status of the vascular region to be examined and must be adapted to the patient's age and body weight. Prior to the radiographic examination, the dosage is determined in accordance with the personal practice of the treating physician.

Contraindications

- Iomeprol solution for injection must not be used in patients with known hypersensitivity to iomeprol or to any of the excipients.
- *Myelography:* In view of the risk of overdose, myelography must not be repeated immediately in the event of a technical failure.
- Examination of the female genital organs during pregnancy or if pregnancy is suspected and in the presence of acute inflammatory processes

Warnings and precautions

General

Anaphylactic reactions may occur during use of iodinated contrast media, under certain circumstances with life-threatening cardiovascular (shock) or respiratory (laryngeal oedema, bronchospasm) and abdominal symptoms, urticaria, angioedema or neurological complications.

For any examination, the personnel requirements must therefore be in place for emergency therapy and the necessary material ready for use (oxygen, adrenaline, infusion material, intubation and ventilation facilities, etc.).

It is absolutely essential to be familiar with the emergency procedures.

In order to avoid extravasation, caution is necessary during the injection of contrast media.

Following administration of contrast media, the patient should remain under observation for another 30 minutes at least because, based on experience, the majority of all serious incidents occur within this period (see “Adverse effects”).

Hydration

Patients must be sufficiently hydrated and relevant disturbances of the fluid or electrolyte balance should be corrected prior to and after administration of the contrast medium. Patients with severe impairment of hepatic or myocardial function, myelomatosis, diabetes mellitus, polyuria, oliguria, hyperuricaemia, sickle cell disease as well as small children, elderly patients and patients with severe systemic diseases in particular should not be exposed to dehydration. Patients with severely impaired hepatic and renal function are also at increased risk. Caution should be exercised when hydrating patients with underlying conditions that might be exacerbated as a result of fluid overload.

Dietary requirements

On the day of the examination, the patient can eat normally unless otherwise instructed by the treating physician.

Hyperthyroidism, nodular goitre

The small amount of inorganic free iodide that may be present *in the contrast medium* might have effects on thyroid function: These effects appear to be more pronounced in patients with latent or overt hyperthyroidism or goitre. There have been reports of thyrotoxic crisis after use of iodinated contrast media.

Kidney disease

Pre-existing renal dysfunction might predispose to the development of acute kidney injury following contrast media administration.
Preventive measures include:

- identification of high-risk patients (especially patients with diabetes mellitus, pre-existing nephropathies and paraproteinaemia)
- ensuring adequate hydration before contrast media administration, preferably by maintaining an i.v. infusion before and during the procedure and until renal clearance of the contrast medium
- whenever possible, avoiding nephrotoxic medicines or major operations or interventions such as renal angioplasty until the contrast medium has been cleared;

- delaying any new examination with contrast media until the renal function values have returned to pre-examination levels.

Patients requiring dialysis may receive the iomeprol injection before dialysis.

Diabetes mellitus

Diabetic nephropathy may predispose to renal dysfunction after intravascular contrast media administration. This may induce lactic acidosis in patients taking biguanides (see also "Interactions").

Multiple myeloma, Waldenström's paraproteinaemia

Myelomatoses and paraproteinaemias are diseases that predispose to renal dysfunction after contrast media administration. Adequate hydration and monitoring of renal function are therefore advisable following contrast media administration.

Phaeochromocytoma

In phaeochromocytoma patients, premedication with alpha- and beta-receptor blockers under the supervision of a physician is recommended before the intra-arterial contrast medium injection in order to prevent a possible hypertensive crisis.

Special patient populations

Neonates, infants, children and adolescents

Infants under one year of age and especially neonates are particularly susceptible to electrolyte disturbances and haemodynamic changes.

Elderly patients

In elderly patients, the risk of reactions with respect to the diminished physiological functions is particularly high, especially when high contrast medium doses are administered. The probability of acute renal insufficiency is increased in these patients.

Hypersensitivity to iodinated contrast media, allergic disposition and asthma

Hypersensitivity or a documented history of a reaction to iodinated contrast media increases the risk of recurrence of a severe reaction to non-ionic contrast media.

Adverse reactions to iodinated contrast media occur more frequently in patients with a history of allergies (such as hay fever, hives and food allergies).

The risk of bronchospasm after contrast media administration is higher in patients with asthma, especially if they are under treatment with beta blockers. Beta blockers can also impair the response to treatment of contrast medium-induced bronchospasm.

Hypersensitivity testing

Even if a small test dose used beforehand has been well tolerated, severe or even fatal reactions can occur during the examination with contrast media.
In patients with a history of life-threatening hypersensitivity reactions to iomeprol or with a confirmed iomeprol allergy (e.g. sensitisation confirmed by skin tests), any further use of iomeprol must be avoided.

Severe cardiovascular diseases

The risk of severe reactions to contrast media is increased in patients with severe heart diseases, particularly in patients with heart failure and coronary artery disease. An intravascular contrast medium injection may induce pulmonary oedema in patients with overt or early heart failure, while contrast media administration can lead to pronounced haemodynamic changes in patients with pulmonary hypertension and heart valve diseases.

CNS disorders

Contrast media administration can exacerbate the neurological symptoms of a degenerative, inflammatory or neoplastic cerebrovascular disease.

An intravascular contrast medium injection may induce vasospasm and resulting manifestations of ischaemia.

Anxiety states

An overt state of agitation, anxiety or malaise may trigger collateral effects or exacerbate reactions to contrast media. In such cases, a sedative may be administered.

Concomitant therapies

Caution is also required in alcoholics and drug addicts because of the possibility of a lowered stimulus threshold.

Any treatment with anticonvulsants must not be stopped, but should be continued without interruption with optimum doses.

Thrombo-embolism risk prevention

A property of non-ionic radiographic contrast media is their low influence on normal physiological functions. *In vitro* studies have shown that non-ionic contrast media have a weaker anticoagulant effect than ionic contrast media in a similar concentration. Medical personnel and support staff should be instructed accordingly in order to avoid prolonged contact between blood and contrast media in the syringe and catheters during angiography, and the catheters must be flushed frequently in order to minimise the risk of thrombo-embolism.

Interactions

Consideration should be given to discontinuing medicines that reduce the seizure threshold until 24 hours have elapsed since the examination with contrast media.

Metformin:
In order to prevent the development of lactic acidosis, treatment with metformin should be discontinued 48 before contrast media administration in diabetes patients undergoing an elective procedure who are under treatment with oral antidiabetic agents of the biguanide class (metformin) and who have moderate kidney disease, and should not be resumed until 48 hours thereafter, provided that the serum creatinine values are unchanged (see “Warnings and precautions”, Special patient populations: Diabetes mellitus).

In emergency patients with impaired or unknown renal function, the physician should assess the benefits and risks of an examination with contrast media and take precautions. Metformin should be discontinued from the time of contrast medium injection. After the examination, the patient should be monitored for signs of lactic acidosis. Treatment with metformin should not be resumed until 48 hours after contrast media administration, provided that the serum creatinine/GFR value has returned to pre-examination levels.

Patients with normal renal function can continue to take metformin as usual.

In patients currently or previously under treatment with interleukin II, the risk of hypersensitivity/delayed reactions (such as fever, chills, rash, flu-like symptoms, retching, vomiting, diarrhoea, hypotension) is increased.

Iodinated contrast media can have effects on diagnostic or therapeutic procedures involving radioactive iodine.

Pregnancy/lactation

Pregnancy and women of childbearing potential

No teratogenicity has been observed following use of iomeprol in animal studies. The clinical relevance of the slightly increased embryotoxicity observed in a peri-postnatal study after iomeprol is unclear (see “Preclinical data”). There are no controlled studies in pregnant women to prove the safety of use in humans. Because exposure to radiation must always be avoided during pregnancy if possible, the benefit of any radiographic examination, with or without contrast media, should be weighed carefully against the potential risk for this reason alone. In the event of exposure to iodinated substances such as iomeprol during pregnancy, the thyroid function of the neonate should be monitored in the first week of life.

Lactation

Following intravenous administration, only a very small amount of iomeprol was transferred into the milk of rats. Iodinated contrast media are also secreted only in small quantities (<1%) in human breast milk. In addition, the absorption of iodinated contrast media via the gastro-intestinal tract in infants is less than 1%. It is therefore assumed that, for the use of iodinated contrast media, it is not necessary to stop breastfeeding.

Effects on ability to drive and use machines

The effects on the ability to drive and use machines have not been assessed. Following intrathecal administration, a period of at least 6 hours should be left before driving a vehicle and using machines.

Adverse effects

The use of iodinated contrast media may lead to adverse effects which are generally mild or moderate and temporary. However, there have also been reports of severe and life-threatening reactions, sometimes resulting in death. In most cases, the reactions occur within minutes of dosing. They can sometimes occur later, however.

Injection site pain and swelling may occur. In most cases, this is attributable to extravasation of the contrast medium. These reactions are generally transient and resolve without long-term consequences. In very rare cases, however, inflammation and even skin necrosis have been observed. In isolated cases, the extravasation resulted in the development of compartment syndrome.

Anaphylaxis (anaphylactoid/hypersensitivity reactions) may manifest with various symptoms. A patient rarely develops all the symptoms. Typically, the patient complains after 1 to 15 minutes (but in rare cases after as long as 2 hours) of abnormal sensation, agitation, flushing, feeling hot, increased sweating, dizziness, increased lacrimation, rhinitis, palpitations, paraesthesia, pruritus, throbbing head, sore throat and throat tightness, dysphagia, cough, sneezing, urticaria, erythema, mild, localised oedema or angioneurotic oedema and dyspnoea due to oedema of the tongue and larynx and/or laryngospasm manifested by wheezing and bronchospasm.

Nausea, vomiting, abdominal pain and diarrhoea are also reported.

These reactions, which can occur irrespectively of the amount administered or the method of administration, may be the first signs of circulatory collapse.

Administration of the contrast medium must be stopped immediately and, if necessary, appropriate specific treatment must be initiated promptly via venous access.

Severe reactions involving the cardiovascular system, such as vasodilation 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 cardiopulmonary resuscitation.

Primary circulatory collapse can occur as the only and/or initial presentation without respiratory symptoms or without other signs or symptoms, as described above.

Vasospasm and consequent ischaemia have been observed during intra-arterial contrast medium injections, in particular after coronary and cerebral angiography. These were often attributable to the procedure and possibly triggered by the catheter tip or excess catheter pressure.

1. Intravascular administration

1.1 Clinical trials

The following frequency definitions are used: Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000).

Nervous system disorders
Uncommon: Headache, dizziness
Rare: Presyncope

Cardiac disorders
Rare: Bradycardia, tachycardia, extrasystoles

Vascular disorders (mainly after cardiovascular treatment/intervention)
Uncommon: Hypertension
Rare: Hypotension

Respiratory, thoracic and mediastinal disorders
Uncommon: Dyspnoea

Gastrointestinal disorders
Uncommon: Nausea, vomiting

Skin and subcutaneous tissue disorders

Uncommon: Erythema, urticaria, pruritus

Rare: Rash

Musculoskeletal and connective tissue disorders

Rare: Back pain

General disorders and administration site conditions

Common: Feeling hot

Uncommon: Chest pain, injection site warmth and pain

Rare: Asthenia, rigor, fever

Investigations

Rare: Raised creatinine levels in the blood

1.2 After market launch

The following adverse effects have been reported after market launch in very rare cases, some in isolated cases.

Blood and lymphatic system disorders

Thrombocytopenia, haemolytic anaemia

Immune system disorders

Anaphylactoid reaction, angioedema, cold sweats, eczema, acute generalised exanthematous pustulosis (AGEP)

Psychiatric disorders

Anxiety, confusion

Nervous system disorders

Coma, transient ischaemic attacks, loss of consciousness, syncope, paralysis, convulsion, dysarthria, paraesthesia, amnesia, somnolence, taste disorder.

Eye disorders

Temporary blindness, visual disturbance, conjunctivitis, increased lacrimation, photopsia.

Cardiac disorders

Cardiac arrest, myocardial infarction, heart failure, angina pectoris, arrhythmia, ventricular or atrial fibrillation, atrioventricular block, cyanosis

Cases of coronary thrombosis have been reported as a complication following coronary catheterisation.

Vascular disorders

Shock, circulatory collapse, flushing, pallor

Respiratory, thoracic and mediastinal disorders

Respiratory arrest, acute respiratory distress syndrome (ARDS), pulmonary oedema, laryngeal oedema, throat oedema, bronchospasm, asthma, cough, throat discomfort, laryngeal discomfort, rhinitis, dysphonia.

Gastrointestinal disorders

Diarrhoea, abdominal pain, salivary hypersecretion, salivary gland enlargement, dysphagia

Skin and subcutaneous tissue disorders

Increased sweating

Renal and urinary disorders

Renal failure

General disorders and administration site conditions

Injection site reactions*, malaise

Investigations

ST segment elevation on the electrocardiogram, abnormal electrocardiogram

*Injection site reactions include pain and swelling at the injection site. These are mostly attributable to extravasation of the contrast medium. These reactions are usually transient in nature and regress completely without sequalae. Cases of extravasation with inflammation and skin necrosis have been reported, even progressing to compartment syndrome.

Cases of vasospasm with resulting ischaemia have been observed during intravascular contrast medium injections, particularly following coronary and cerebral angiography. These were often attributable to the procedure and possibly triggered by the catheter tip or excess catheter pressure.

As with other iodinated contrast media, there have been very rare reports of mucocutaneous syndromes, including Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell syndrome) and erythema multiforme following administration of iomeprol.

1.3 Children and adolescents

The experience with administration in children and adolescents is limited. The database on safety in children and adolescents from clinical trials includes 167 patients. The safety profile of Iomeron is similar in children and adults.

2. Intrathecal administration

The adverse effects reported most frequently following intrathecal administration of iomeprol are headache, dizziness, nausea, vomiting and back pain. These effects are usually of mild-to-moderate severity and of a transient nature. Headaches may persist for a few days in rare cases.

After intrathecal administration, adverse effects occur mainly a few hours (3 to 6 hours, see "Pharmacokinetic properties") after the examination as a result of the contrast medium passing from the cerebrospinal fluid into the vascular space. Most reactions usually develop within 24 hours after the injection.

2.1 Clinical trials

The following adverse effects have been reported in patients treated with iomeprol in clinical trials:

Nervous system disorders
Very common: Headache (16.7%)
Common: Dizziness
Uncommon: Loss of consciousness, paraparesis, paraesthesia, hypaesthesia, somnolence

Vascular disorders
Common: Hypertension
Uncommon: Hypotension, flushing

Gastrointestinal disorders
Common: Nausea, vomiting

Skin and subcutaneous tissue disorders

Uncommon: Increased sweating, pruritus

Musculoskeletal and connective tissue disorders

Common: Back pain, limb pain

Uncommon: Muscle stiffness, neck pain

General disorders and administration site conditions

Common: Injection site reaction*

Uncommon: Warmth, fever

2.2 After market launch

Immune system disorders

Anaphylactoid reaction

Nervous system disorders

Epilepsy

Skin and subcutaneous tissue disorders

Rash

*Injection site reactions include pain at the injection site and discomfort, pain and warmth at the injection site.

2.3 Children and adolescents

Neither in clinical trials nor in post-marketing studies have adverse effects been reported following intrathecal administration of Iomeron.

3. Administration into body cavities

After injection of an iodinated contrast medium into body cavities, most reactions occur some hours after contrast media administration as a result of low absorption from the administration site.

Raised blood amylase levels are common after ERCP. Very rare cases of pancreatitis have been described.

Reactions that have been reported in connection with arthrography and fistulography are usually irritative manifestations superimposed on pre-existing states 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 ruled out (see above under "Anaphylaxis" regarding anaphylactoid reactions).

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

Overdose

An overdose may lead to life-threatening adverse reactions, particularly involving the respiratory, cardiovascular and renal systems. Any overdose must be treated very quickly and symptomatically, based on the maintenance of all vital functions. Iomeprol does not bind to plasma/serum proteins, and is therefore dialyzable.

In the event of an accidental intrathecal overdose (see "Dosage/administration"), the following signs and symptoms of a CNS disorder may occur: ascending hyperreflexia or tonic-clonic spasms through to generalised seizures, hyperthermia, stupor and respiratory depression.

Properties/effects

ATC code: V08AB10

Mechanism of action

Iomeron is a non-ionic, tri-iodinated contrast medium that has a particularly low osmolality and viscosity. A range of formulations of iomeprol has been established in a wide range of concentrations (up to 400 mg iodine/ml). The physical and chemical properties of Iomeron solutions for injection in various concentrations are listed below:

Iodine concentration (mg/ml)	Osmolality at 37 °C (mOsm/kg H_2O)	Viscosity at 37 °C (mPa•s)
Iomeron 250	435 ± 20	2.9 ± 0.3
Iomeron 300	521 ± 24	4.5 ± 0.4
Iomeron 350	618 ± 29	7.5 ± 0.6
Iomeron 400	726 ± 34	12.6 ± 1.1

The pH of the solution is 7.0-7.2

Pharmacokinetic properties

Absorption, distribution, metabolism, elimination

The pharmacokinetic properties of iomeprol administered via the intravascular route follows a two-compartment model, with a rapid distribution and slower elimination phase.

The volume of distribution (V_D) is 0.28 l/kg.

In 18 healthy volunteers, the mean distribution and elimination half-lives of iomeprol were 23 ± 14(s) min and 109 ± 20(s) min respectively; the rate of elimination via the urinary tract reached 50% in the course of 2 hours after administration.

In vitro studies show that there is no binding to plasma proteins.

Kinetic properties in special patient populations

There are no data on the kinetic properties in particular clinical situations (e.g. In the presence of hepatic or renal insufficiency). Because no controlled studies in animals or in nursing mothers are available, it is not known whether iomeprol is transferred to breast milk.

Preclinical data

The results of studies in rats, mice and dogs show acute intravenous/intra-arterial toxicity for iomeprol similar to that of other non-ionic contrast media.

Experimental studies of systemic tolerability in rats and dogs following repeated (once daily over 28 days) intravenous administration in a dosage of 1.0 g iodine/kg showed no significant changes to suggest that iomeprol should not be used diagnostically in humans.

In vivo and *in vitro* tests for genotoxic effects (gene, chromosome and genome mutation tests) yielded no evidence of iomeprol having mutagenic or chromosome-damaging potential.

Reproduction studies in rats and rabbits yielded no evidence of impairment of fertility or teratogenicity. A peri-postnatal study showed a slightly increased mortality rate in neonates at 4 g (iodine)/kg. The clinical relevance of this finding is not clear.

The local tolerability tests were carried out in rats following subcutaneous and intramuscular and in rabbits following intramuscular injection.

Iomeprol does not induce any local reactions following subcutaneous administration, although intramuscular administration leads to oedema and hyperaemia, particularly in rabbits. These largely reversible changes are comparable to those observed following injection of hyperosmolar NaCl solution (0.7 osmol/kg).

Additional information

Incompatibilities

Mixtures with other solutions for injection must be avoided. Because Iomeron, like all iodinated radiographic contrast media, can react with copper surfaces (e.g. brass), any potential contact between the solution and such materials or similar products should be ruled out.

Influence on diagnostic methods

Thyroid function testing: After administration of an iodinated contrast medium, the radio-isotope uptake value in the thyroid tissue decreases for a period of time that may last for 2 weeks or more. High concentrations of the contrast medium in the serum or urine can interfere with laboratory test results such as bilirubin, proteins or inorganic substances such as iron, copper, calcium, potassium and phosphates.

Shelf-life

The medicinal product must not be used after the date which is stated on the pack after “EXP”.

Special precautions for storage

Store away from light. Store at room temperature (15-25 °C).
Keep out of the sight and reach of children.

Instructions for handling

The contrast medium containers are not intended for the withdrawal of multiple doses. The rubber stopper should never be pierced more than once. We recommend the use of withdrawal cannulas to pierce the stopper and draw up the contrast medium. Once the vial has been opened, the solution should be used immediately. The contrast medium should be drawn up only immediately before use. Residues of the contrast medium must be disposed of because the solution is no longer sterile.

The following additional instructions apply to use of the 500 ml bottle:

The contrast medium must be used only in conjunction with an Injectomat. Disposable injector system articles must be discarded after each examination.

Supplementary instructions provided by the relevant equipment manufacturer must be followed.

Marketing authorisation number

53255, 53602 (Swissmedic).

Pack sizes

Iomeron 250 mg/ml, 50 ml vial: 1, 10

Iomeron 250 mg/ml, 100 ml vial: 1, 10

Iomeron 300 mg/ml, 50 ml vial: 1,10

Iomeron 300 mg/ml, 100 ml vial: 1, 10

Iomeron 300 mg/ml, 200 ml vial: 1, 10

Iomeron 300 mg/ml, 500 ml vial: 1, 6

Iomeron 350 mg/ml, 50 ml vial:	1, 10
Iomeron 350 mg/ml, 100 ml vial:	1, 10
Iomeron 350 mg/ml, 200 ml vial:	1, 10
Iomeron 350 mg/ml, 500 ml vial:	1, 6
Iomeron 400 mg/ml, 50 ml vial:	1, 10
Iomeron 400 mg/ml, 100 ml vial:	1, 10
Iomeron 400 mg/ml, 150 ml vial:	1, 10
Iomeron 400 mg/ml, 200 ml vial:	1, 10
Iomeron 400 mg/ml, 500 ml vial:	1, 6

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Marketing authorisation holder

Bracco Suisse SA, Cadempino.

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