AUSTRALIAN PRODUCT INFORMATION

UROGRAFIN® (Sodium amidotrizoate / Amidotrizoate meglumine)

1 NAME OF THE MEDICINE

Sodium amidotrizoate / Amidotrizoate meglumine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Urografin 30% contains 40 mg/mL sodium amidotrizoate and 260 mg/mL amidotrizoate meglumine in aqueous solution.

Urografin 76% contains 100 mg/mL sodium amidotrizoate and 660 mg/mL amidotrizoate meglumine in aqueous solution.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Aqueous solution

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Intravenous and retrograde urography. Computerized tomography.

Also for all angiographic examinations as well as for amniography, arthrography, intraoperative cholangiography, fistulography, hysterosalpingography, splenoportography, vesiculography and others.

Urografin is not to be used for myelography, ventriculography of cisternography, since it is likely to provoke neurotoxic symptoms in these examinations.

4.2 DOSE AND METHOD OF ADMINISTRATION

General information

- Dietary suggestions

In the case of abdominal angiography and urography, the diagnostic yield is increased if the bowels are emptied of faecal matter and gas. On the two days prior to the examination patients should therefore avoid flatulent food, in particular peas, beans and lentils, salads, fruit, dark and fresh bread and all kinds of uncooked vegetables. On the day before the examination, patients should refrain from eating after 6 p.m. Moreover, it can be appropriate to administer a laxative in the evening. In babies and young children, however, prolonged fasting and the administration of a laxative before the examination are contraindicated.

- Hydration

Adequate hydration must be assured before and after contrast medium administration. This applies especially to patients with multiple myeloma, diabetes mellitus and nephropathy, polyuria, oliguria, hyperuricaemia, as well as to newborns, infants, small children and elderly patients. Disturbances of the water and electrolyte balance must be corrected before the examination.

- Newborns (< 1 month) and infants (1 month – 2 years)

Young infants (age < 1 year) and especially newborns are susceptible to electrolyte imbalance and haemodynamic alterations. Care should be taken regarding the dose of contrast medium to be given, the technical performance of the radiological procedure and the patient status.

- Pretesting

Sensitivity testing using a small test dose of contrast medium is not recommended, as it has no predictive value. Furthermore, sensitivity testing itself has occasionally led to serious and even fatal hypersensitivity reactions.

The contrast medium solution should not be drawn into the syringe or the infusion bottle attached to the infusion set until immediately before the examination.

Vials containing contrast medium solutions are not intended for the withdrawal of multiple doses. The rubber stopper should never be pierced more than once. The use of cannulas with a long tip and a diameter of maximally 18 G is recommended for piercing the stopper and drawing up the contrast medium (dedicated withdrawal cannulas with a side hole, e.g. Nocore-Admix cannulas, are particularly suitable).

Contrast medium solution not used in one examination session must be discarded.

The patient must attend for examination fasting but adequately hydrated. Disorders of the water and electrolyte balance must be corrected. This applies in particularly to patients who are predisposed to such disturbances.

- Anxiety

Experience shows that pronounced states of excitement and anxiety can be the cause of side effects or intensify contrast medium-related reactions. They can be counteracted by calm management and the use of suitable drugs.

Warming prior to use

Experience shows that contrast medium is tolerated better if it is warmed to body temperature.

Warnings for intravascular use

Intravascular administration of contrast media should, if possible, be done with the patient lying down. After the administration, the patient should be kept under observation for at least 30 minutes, since experience shows that the majority of all severe incidents occur within this time.

The dosage may vary depending on the age, weight, cardiac output and general condition of the patient.

In patients suffering from marked renal or cardiovascular insufficiency, and in patients in a poor general condition, the contrast medium dose must be kept as low as possible. In these patients it is advisable to monitor renal function for at least 3 days following the examination.

Should diagnostic clarification necessitate several high single doses, the opportunity should be given between injections to compensate for the increased serum osmolarity by the influx of interstitial fluid.

To achieve this, a period of 10-15 minutes is necessary in adequately hydrated patients. The intravascular administration of water and electrolytes is indicated if more than 300mL contrast medium are required for a single examination.

Recommended doses:

- **Intravenous urography**

Urografin 76% is used for intravenous urography. In general, the rate of injection is 20mL/minute. If patients with cardiac insufficiency are given 100mL or more, an injection time of 20-30 minutes is recommended.

◊ Dosage

Adults

The dose is 20mL Urografin 76%. Increasing the dose to 50mL considerably increases the diagnostic yield. The dose may be increased yet again if this is considered necessary in special indications.

Children

The physiologically weak concentrating ability of the still immature nephron of infantile kidneys necessitates relatively high doses of Urografin 76%:

Up to 1 year	7 - 10mL
1 - 2 years	10 - 12mL
2 - 6 years	12 - 15mL
6 - 12 years	15 - 20mL
over 12 years	adult dose

◊ Filming times

The renal parenchyma can be demonstrated best when the film is taken immediately after the end of the administration.

For visualization of the renal pelvis and urinary tract, the first film is taken 3-5 and the second 10-12 minutes after the administration of the contrast medium. In young patients one should generally choose the earlier and in older patients the later times.

In babies and young children it is advisable to take the first film as soon as about 2 minutes after the administration of the contrast medium.

Insufficient contrast can necessitate later films.

- **Infusion urography**

◊ Dosage

Adults and adolescents

1 bottle of 100mL Urografin 76% or 1 bottle of 250mL Urografin 30%.

In general, the infusion time should not be less than 5 minutes nor much more than 10 minutes. Infusion times of 20-30 minutes are indicated in patients with cardiac insufficiency.

Children	Urografin 30%
3 - 12 months	6mL/kg body weight
1 - 8 years	4mL/kg body weight
over 8 years	3mL/kg body weight

Infusion time: 8 - 10 minutes

Compression is contraindicated in babies and is also inadvisable during the infusion of large amounts of contrast medium in children, adolescents and adults, since, if drainage is obstructed, the increased diuresis can lead to rupture of the fornix as a result of the high pressure. Compression may, however, be applied about 10 minutes after the end of the infusion to demarcate organic from functional filling defects.

◊ Filming times

The first film should be taken towards the end of the infusion. Further films may be taken within the next 20 minutes (or later in case of excretory disturbances).

- **Retrograde urography**

Because of its good tissue tolerance Urografin 30% is especially well suited for retrograde urography. It is advisable to warm the contrast medium to body temperature to avoid low-temperature stimulus and resultant ureteral spasms.

- **Angiography**

Urografin 76% is also suitable for angiographic examinations, preferably for those which require a particularly high iodine concentration, e.g. aortography, angiocardiography, coronary arteriography. The dosage depends on age, weight, cardiac output, general state of health, the clinical problem, examination technique, kind and volume of the region to be examined.

Consult special literature for further indications.

4.3 CONTRAINDICATIONS

Manifest hyperthyroidism, decompensated cardiac insufficiency.

Hysterosalpingography must not be performed during pregnancy or in the presence of acute inflammatory processes in the pelvic cavity.

Endoscopic retrograde cholangiopancreatography (ERCP) is contraindicated in acute pancreatitis.

Urografin is not to be used for myeolography, ventriculography or cisternography, since it is likely to provoke neurotoxic symptoms (pain, convulsions and coma, often with lethal outcome) in these examinations.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The need for examination merits particularly careful consideration in hypersensitivity to iodinated contrast media, severe impairment of hepatic or renal function, cardiac and circulatory insufficiency, pulmonary emphysema, poor general health, cerebral arteriosclerosis, diabetes mellitus requiring treatment, cerebral spasmodic conditions, latent hyperthyroidism, bland nodular goiter and multiple myeloma.

Fluid intake should not be restricted before the use of hypertonic contrast media in patients with multiple myeloma, diabetes mellitus requiring treatment, polyuria, oliguria or gout and in babies, young children and patients in a very poor general state of health.

The following precautions apply to any mode of administration, however the risks mentioned are higher in intravascular administration.

- Hypersensitivity

Occasionally, allergy like hypersensitivity reactions have been observed after use of X-ray contrast media such as Urografin (see Section 4.8 Adverse Effects). These reactions are usually manifest as non-serious respiratory or cutaneous symptoms, as mild respiratory distress, reddening of the skin (erythema), urticaria, itching or facial edema. Serious events such as angioedema, subglottic edema, bronchospasm and allergic shock are possible. Generally these reactions occur within one hour after administration of contrast media. However, in rare cases delayed reactions may occur (after hours to days).

Patients with hypersensitivity or a previous reaction to iodinated contrast media are at increased risk of having a severe reaction.

Before any contrast medium is injected, the patient should be questioned for a history of allergy (e.g. seafood allergy, hay fever, hives), sensitivity to iodine or to radiographic media and bronchial asthma as the reported incidence of adverse reactions to contrast media is higher in patients with these conditions and premedication with antihistamines and/or glucocorticoids may be considered. However contrast media and prophylactic agents should not be administered together.

Patients with bronchial asthma are at special risk of having bronchospasms or a hypersensitivity reaction.

If hypersensitivity reactions occur (see Section 4.8 Adverse Effects), administration of the contrast medium must be discontinued immediately and if necessary specific therapy instituted via a venous access. It is therefore advisable to use a flexible indwelling cannula for intravenous contrast medium administration. To permit immediate countermeasures to be taken in emergencies, appropriate drugs, an endotracheal tube and a respirator should be ready at hand.

- Thyroid dysfunction

The small amount of free inorganic iodide from iodinated contrast media might interfere with thyroid function. Therefore, the need for examination merits particularly careful consideration in patients with latent hyperthyroidism or goiter.

In neonates, especially preterm infants, who have been exposed to Urografin, either through the mother during pregnancy or in the neonatal period, it is recommended to monitor thyroid function, as an exposure to excess iodine may cause hypothyroidism, possibly requiring treatment.

- 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.

- Very poor state of health

The need for examination merits particularly careful consideration in patients with very poor general state of health.

Intravascular use

- Renal failure

Temporary renal failure may occur in rare cases. Preventative measures against acute renal failure following contrast medium administration include:

Identification of high risk patients, e.g. patients with: a history of renal disease, pre-existing renal insufficiency, previous renal failure after contrast medium administration, diabetes mellitus and nephropathy, volume depletion, multiple myeloma, age greater than 60 years, advanced vascular disease, paraproteinemia, severe and chronic hypertension, gout, patients receiving large or repeated doses.

Ensuring adequate hydration in risk patients before contrast medium administration preferably by maintaining intravascular infusion before and after the procedure and until the contrast medium has been cleared by the kidneys.

Avoiding additional strain on the kidneys in the form of nephrotoxic drugs, oral cholecystographic agents, arterial clamping, renal arterial angioplasty, major surgery etc, until the contrast medium has been cleared.

Postponing a new contrast medium examination until renal function returns to pre-examination levels.

- Metformin therapy

The use of renally excreted intravascular X-ray contrast media can lead to transient impairment of kidney function. This may result in lactic acidosis in patients who are taking biguanides (As a precaution, biguanides should be stopped 48 hours before until at least 48 hours after contrast medium administration and reinstated only after normal renal function has been regained).

- Cardiovascular disease

In patients with valvular disease and pulmonary hypertension contrast medium administration may lead to pronounced hemodynamic changes. Reactions involving ischemic ECG changes and major arrhythmia are more common in older patients and in those with preexisting cardiac disease.

The intravascular injection of contrast media may precipitate pulmonary edema in patients with heart failure.

- CNS disorders

Particular care should be paid to the intravascular administration of contrast media in patients with acute cerebral infarction, acute intracranial hemorrhage, and other conditions involving blood-brain barrier damage, cerebral edema or acute demyelination. Intracranial tumours or metastases and a history of epilepsy may increase the incidence of convulsive seizures after administration of iodinated contrast media. Neurological symptoms due to cerebrovascular diseases, intracranial tumours or metastases, degenerative or inflammatory pathologies may be exacerbated by contrast medium administration. Vasospasm and subsequent cerebral ischemic phenomena may be caused by intraarterial injections of contrast media. Patients with symptomatic cerebrovascular diseases, recent stroke or frequent transient ischemic attacks have an increased risk of neurological complications.

- Severe liver dysfunction

In the case of severe renal insufficiency the coexistence of severe hepatic dysfunction can seriously delay contrast medium excretion, possibly necessitating haemodialysis.

- Myeloma and paraproteinemia

Myeloma or paraproteinemia may predispose to renal impairment following contrast medium administration. Adequate hydration is mandatory.

- Pheochromocytoma

Patients with pheochromocytoma may develop a severe (occasionally uncontrollable) hypertensive crisis following intravascular contrast medium use. Premedication with alpha-receptor blockers is recommended.

- Patients with autoimmune disorders

Cases of severe vasculitis or Stevens-Johnson like syndrome have been reported in patients with preexisting autoimmune disorders.

- Myasthenia gravis

The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis.

- Alcoholism

Acute or chronic alcoholism may increase blood-brain barrier permeability. This facilitates the passage of the contrast medium into cerebral tissue, possibly leading to CNS reactions. Caution must also be exercised in alcoholics and drug addicts because of the possibility of a reduced seizure threshold.

- Coagulation

Ionic iodinated contrast media inhibit blood coagulation *in vitro*, more than non-ionic contrast media. Nevertheless medical personnel performing vascular catheterization procedures should consider that numerous factors in addition to the contrast medium, including length of procedure, number of injections, catheter and syringe material, underlying disease state, and concomitant medication may contribute to the development of thromboembolic events. Therefore, when performing vascular catheterization procedure one should be aware of this and pay meticulous attention to the angiographic technique and flush the catheter frequently with physiological saline (if possible with the addition of heparin) and minimize the length of the procedure so as to minimize the risk of procedure-related thrombosis and embolism.

The use of plastic syringes in place of glass syringes has been reported to decrease but not eliminate the likelihood of *in vitro* clotting.

Caution is advised in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Use in body cavities

The possibility or pregnancy must be excluded before performing hysterosalpingography.

Inflammation of the bile ducts or salpinx may increase the risk of reactions following cholangiography, ERCP or hysterosalpingography procedures.

Premedication with alpha-receptor blockers is recommended in phaeochromocytoma patients because of the risk of blood pressure crises.

Use in the elderly

Underlying vascular pathology and neurological disorders often seen in the elderly constitute an increased risk of adverse reactions to iodinated contrast media.

Paediatric use

See 'Use in paediatrics' in Section 4.6 Fertility, Pregnancy and Lactation.

Effects on laboratory tests

Interference with diagnostic tests

Following the administration of iodinated renal contrast media, the capacity of the thyroid tissue to take up radioisotopes for diagnosing disorders of the thyroid is reduced for up to 2 weeks, and even longer in individual cases.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Hypersensitivity reactions can be aggravated in patients on beta-blockers particularly in the presence of bronchial asthma. Moreover, it should be considered that patients on beta-blockers may be refractory to standard treatment of hypersensitivity reactions with beta agonists.

The prevalence of delayed reactions (e.g. fever, rash, flu-like symptoms, joint pain and pruritus) to contrast media is higher in patients who have received interleukin.

Diabetic nephropathy may predispose to renal impairment following intravascular contrast medium administration. This may precipitate lactic acidosis in patients who are taking biguanides. As a precaution, biguanides should be stopped 48 hours prior to the contrast medium examination and reinstated only after adequate renal function has been regained.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

It has not yet been demonstrated that Urografin is safe for use in pregnant patients. Since, where possible, radiation stress should in any case 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.

Caution should be exercised when using Urografin in pregnant women. See also Section 4.4 Special Warnings and Precautions for Use, subsection 'Thyroid dysfunction', and Use in paediatrics.

Use in lactation

It is not known whether Urografin enters the breast milk. See also Section 4.4 Special Warnings and Precautions for Use, subsection 'Thyroid dysfunction', and Use in paediatrics.

Use in paediatrics

In neonates, especially preterm infants, who have been exposed to Urografin, either through the mother during pregnancy or in the neonatal period, it is recommended to monitor thyroid function, as an exposure to excess iodine may cause hypothyroidism, possibly requiring treatment. See also Section 4.4 Special Warnings and Precautions for Use, subsection 'Thyroid dysfunction'.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

As with all iodinated contrast media, in rare cases there is a possibility of delayed reactions following contrast medium administration that could impair the ability to drive and use machines.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

In order to give an approximate indication of incidence of the following definitions apply when the words "common", "uncommon" and "rare" appear in the text:

- common incidence $\geq$ 1: 100
- uncommon incidence < 1: 100, but $\geq$ 1: 1000
- rare incidence < 1: 1000

Intravascular use

Side effects in association with the intravascular use of iodinated contrast media are usually mild to moderate and temporary, although severe and life-threatening reactions, even fatal ones, have also been observed.

Nausea, vomiting, erythema, a sensation of pain and a general feeling of warmth are the most frequently recorded reactions on intravascular administration. Subjective complaints such as sensations of warmth or nausea can usually be alleviated quickly by reducing the rate of administration or interrupting the administration briefly.

- Anaphylactoid reactions/hypersensitivity

Mild angioedema, conjunctivitis, coughing pruritus, rhinitis, sneezing and urticaria have been reported commonly. These reactions, which can occur irrespective of the amount administered and the mode of administration, may be the first signs of incipient state of shock.

Experience shows that hypersensitivity reactions occur more frequently in patients with an allergic disposition.

Severe reactions requiring emergency treatment can occur in the form of a circulatory reaction accompanied by peripheral vasodilatation and subsequent hypotension, reflex tachycardia, dyspnoea, agitation, confusion and cyanosis and possibly leading to unconsciousness.

Hypotension, bronchospasm and laryngeal spasm or edema occurs uncommonly.

Delayed reactions can occasionally occur.

Paravascular administration of the contrast medium rarely leads to severe tissue reactions.

- Body as a whole

Heat sensations and headache have been reported as being common. Malaise, chills or sweating and vasovagal reactions are uncommon.

In rare cases alterations in body temperature and swelling of salivary glands are possible.

- Respiratory

Transient disturbances in respiratory rate, dyspnea and respiratory distress and coughing are common.

Respiratory arrest and pulmonary edema are rare reactions.

- Cardiovascular

Clinically relevant transient disturbance in heart rate, blood pressure, disturbance in cardiac rhythm or function and cardiac arrest are uncommon.

Severe reactions requiring emergency treatment can occur in the form of a circulatory reaction accompanied by peripheral vasodilatation and subsequent hypotension, reflex tachycardia, dyspnea, agitation, confusion and cyanosis possibly leading to unconsciousness. Serious thromboembolic events causing myocardial infarction have been reported in rare cases.

- Gastrointestinal

Nausea and vomiting are common reactions. Abdominal pain has been reported as being uncommon.

- Cerebrovascular

It is known that cerebral angiography and other procedures in which the contrast medium reaches the brain with the arterial blood can be accompanied by transient neurological complications such as: dizziness, headache, coma, amnesia, photophobia, temporary states, agitation or confusion and somnolence, convulsions, transient pareses/paralysis, tremor, disturbed speech, temporary blindness, vision or slack facial muscles and - particularly in epileptics and patients with focal brain damage - epileptic fits are uncommon. Very rarely, the induction of fits in these patients has been described on intravenous administration of the contrast medium as well.

Serious, in isolated cases fatal, thromboembolic events causing stroke have been reported on rare occasions.

- Renal

Temporary renal failure may occur in rare cases.

- Skin

Mild angioedema, flush reaction with vasodilatation, urticaria, pruritus and erythema have been commonly observed.

Toxic skin reactions such as the mucocutaneous syndrome (e.g. Stevens-Johnson's or Lyell syndrome) may develop in rare cases.

- Local irritation (injection site)

Local pain occurs commonly mainly in peripheral angiography. Extravasation of contrast media including Urografin gives rise to local pain, and edema, but usually recedes without sequela. However inflammation and even tissue necrosis have been seen on very rare occasions. Thromophlebitis and venous thrombosis are uncommon.

Use in body cavities

Reactions after the administration into body cavities are rare. The majority of them occur some hours after the administration due to the slow absorption from the area of administration

and distribution in the whole organism primarily through diffusion controlled processes.

Some elevation of amylase levels is common following ERCP. Acinar opacification following ERCP has been shown to be associated with an increased risk of post ERCP pancreatitis. Rare cases of necrotizing pancreatitis have been described.

In connection with hysterosalpingography, cases of vasovagal reactions are uncommon.

- Anaphylactoid reactions/hypersensitivity

Systemic hypersensitivity is rare, mostly mild and occurs generally in the form of skin reactions. However, the possibility of a severe hypersensitivity reaction cannot be totally excluded.

Adverse drug reactions from post-marketing spontaneous reports

- Endocrine disorders

Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been reported with unknown frequency following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

In the event of accidental intravascular overdose in humans, the water and electrolyte losses must be compensated by infusion. Renal function needs monitoring for at least the next 3 days.

If needed, hemodialysis can be used to eliminate the bulk of the contrast medium from the patient's system.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

No data available

Clinical trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

No data available

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Urografin also contains sodium calcium edetate and water for injections.

6.2 INCOMPATIBILITIES

Contrast media must not be mixed with any other drugs to avoid the risk of possible incompatibilities.

6.3 SHELF LIFE

5 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C

Protect from light and secondary X-rays.

6.5 NATURE AND CONTENTS OF CONTAINER

Urografin 30%:

10 x 10 mL in glass ampoule

1 x 250 mL in glass bottle

Urografin 76%:

10 x 50 mL in glass bottle

10 x 100 mL in glass bottle

Not all presentations may be marketed in Australia.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

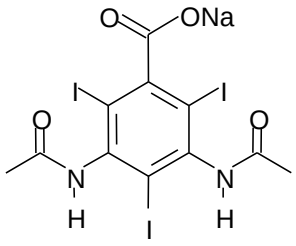
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

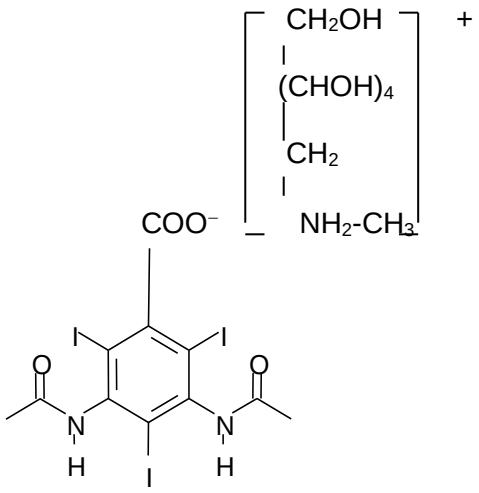
	Molecular formula	Chemical name	Molecular weight	Solubility in water
Sodium amidotrizoate (CAS No. 737-31-5)	$C_{11}H_8I_3N_2NaO_4$	Sodium 3,5-diacetamido-2,4,6-triiodobenzoate	635.90	Freely soluble
Amidotrizoate meglumine (CAS No. 131-49-7)	$C_{18}H_{26}I_3N_3O_9$	N-methylglucamine 3,5-diacetamido-2,4,6-triiodobenzoate	809.13	Freely soluble

Chemical structure

Sodium amidotrizoate



Amidotrizoatemeglumine



Physico-chemical properties

Urografin	30%	76%
Iodine concentration (mg/mL)	146	370
Iodine content (g) per		
ampoule of 10mL	1.46	-
bottle of 50mL	-	18.5
bottle of 100mL	-	37.0
bottle of 250mL	36.5	-
Contrast medium concentration (mg/mL)	300	760
Contrast medium content (g) per		
ampoule of 10mL	3.0	-
bottle of 50mL	-	38.0
bottle of 100mL	-	76.0
bottle of 250mL	75.0	-
Viscosity (mPa . s or cP)		
at 20°C	2.2	18.5
at 37°C	1.4	8.9
Osmotic pressure at 37°C		
(MPa)	1.78	5.4
(atm)	17.6	53.3
Osmolality at 37°C		
(osm/kg H_2O)	0.71	2.1

CAS number

Sodium amidotrizoate (CAS No. 737-31-5)

Amidotrizoate meglumine (CAS No. 131-49-7)

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not Scheduled

8 SPONSOR

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
PYMBLE NSW 2073

www.bayer.com.au

9 DATE OF FIRST APPROVAL

22 September 1992 - Urografin 30% (10 mL ampoule, 250 mL bottle) and Urografin 76% (50 mL bottle)
8 June 1994 - Urografin 76% (100 mL bottle)

10 DATE OF REVISION

14 June 2018

Summary table of changes

Section changed	Summary of new information
All sections	Reformatted into the SmPC format.
4.4	Addition of warning to monitor thyroid function as excess iodine may cause neonatal hypothyroidism.
4.6	Addition of a Use in paediatrics section to include a recommendation to monitor thyroid function, as an exposure to excess iodine may cause hypothyroidism.
4.8	Addition of details of reports of adverse drug reactions indicative of hypothyroidism following iodinated contrast media administration.
6.2	Addition of instruction that contrast media is not to be mixed with other drugs.
6.3	Addition of the registered shelf life.