

# DATA SHEET

## 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

Solution for injection or infusion.

### 4. CLINICAL PARTICULARS

#### 4.1 THERAPEUTIC INDICATIONS

Intravenous and retrograde urography.

Also for all angiographic examinations as well as for amniography, arthrography, intraoperative cholangiography, endoscopic retrograde cholangiopancreatography (ERCP), sialography, fistulography, hysterosalpingography, splenoportography, vesiculography and others.

**Urografin is not to be used for myelography, ventriculography or 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, 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 pm. 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 with nephropathy, polyuria, oliguria, hyperuricaemia, as well as to newborns, infants, small children and elderly patients. Disorders 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.

- **Instructions for Use/Handling**

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. Contrast media should not be used in case of severe discoloration, the occurrence of particulate matter or defective container.

Vials containing contrast medium solutions are not intended for the withdrawal of multiple doses. The rubber stopper should never be pierced more than once to prevent large amounts of microparticles from the stopper getting into the solution. The use of cannulas with a long tip and a maximum diameter of 18 G is recommended for piercing the stopper and drawing up the contrast medium (dedicated withdrawal cannulas with a lateral aperture, 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 particular to patients who are predisposed to such disturbances.

- **Anxiety**

Pronounced states of excitement and anxiety may increase the risk 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**

Contrast media, which are warmed to body temperature before administration, are better tolerated and can be injected more easily because of reduced viscosity.

Using an incubator, only the calculated number of bottles needed for the same examination day should be warmed up to 37°C. If protected from daylight, longer periods of warming have shown no change in chemical purity. However, three months must not be exceeded.

### **Dosage 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**

• **Injection**

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

Adults

The dose is 20 mL Urografin 76%. Increasing the Urografin 76% dose to 50 mL 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%:

<b>up to 1 year</b>	7 - 10 mL
<b>1 - 2 years</b>	10 - 12 mL
<b>2 - 6 years</b>	12 - 15 mL
<b>6 - 12 years</b>	15 - 20 mL
<b>above 12 years</b>	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 minutes 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**

Adults and Adolescents

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

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

1 bottle of 250 mL Urografin 30% for infusion.

<b>3 - 12 months</b>	6 mL/kg body weight
<b>1 - 8 years</b>	4 mL/kg body weight
<b>Over 8 years</b>	3 mL/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.

**Administration into body cavities**

**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.

Urografin 76% solution may also be used if greater opacification is desirable for special examinations. Signs of irritation are observed extremely rarely despite the high concentration.

**Angiography**

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

**Other Body Cavities**

During arthrography, hysterosalpingography and especially ERCP, injections of contrast medium should be monitored by fluoroscopy. 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 myelography, 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 SPECIAL 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 goitre 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 warnings and 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 oedema. Serious events such as angioedema, subglottic oedema, 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 (Undesirable 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 medicines, an endotracheal tube and a respirator should be ready at hand.

### ***Thyroid dysfunction***

Particularly careful risk-benefit assessment is required in patients with known or suspected hyperthyroidism or goitre, as iodinated contrast media may interfere with thyroid function, aggravate or induce hyperthyroidism and thyrotoxic crisis. Testing of thyroid function prior to Urografin administration and/or preventive thyreostatic medication may be considered in patients with known or suspected hyperthyroidism.

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 a very poor general state of health.

### ***Intravascular Use***

- ***Renal Failure***

Temporary renal failure may occur in rare cases. Preventive 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 with 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 medicines, 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.

Patients on dialysis may receive contrast media for radiological procedures as iodinated contrast media are cleared by the dialysis process.

- ***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 haemodynamic changes. Reactions involving ischaemic ECG changes and major arrhythmia are more common in older patients and in those with pre-existing cardiac disease.

The intravascular injection of contrast media may precipitate pulmonary oedema 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 haemorrhage, and other conditions involving blood - brain barrier damage, cerebral oedema 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 ischaemic phenomena may be caused by intraarterial injections of contrast media. Patients with symptomatic cerebrovascular diseases, recent stroke or frequent transient ischaemic 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 because of the risk of blood pressure crises.

- **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 of 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.

### **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 contrast media, the capacity of the thyroid tissue to take up radioisotopes for diagnosing disorders of the thyroid is reduced for up to two weeks and even longer in individual cases.

## **4.5 INTERACTION 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, wherever possible, radiation exposure should be avoided during pregnancy, the benefits of any X-ray examination, with or without contrast media, should 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, 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 use of iodinated intravascular contrast media are usually mild to moderate and transient in nature. However, severe and life-threatening reactions as well as deaths have been reported.

Nausea, vomiting, a sensation of pain and a general feeling of warmth are the most frequently recorded reactions. 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 (see section 4.4 Special Warnings and Precautions for Use).

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 possibly leading to unconsciousness.

Hypotension, bronchospasm and laryngeal spasm or oedema occur 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 disturbance in respiratory rate, dyspnoea and respiratory distress and coughing are common.

Respiratory arrest and pulmonary oedema 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, dyspnoea, 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 in high concentrations with the arterial blood can be accompanied uncommonly by transient neurological complications. These include dizziness, headache, coma, amnesia, photophobia, agitation or confusion and somnolence, convulsions, transient paresis/paralysis, tremor, disturbed speech, hearing, temporary blindness, vision or slack facial muscles and – particularly in epileptics and patients with focal brain damage – epileptic fits.

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 oedema, but usually recedes without sequela. However, inflammation and even tissue necrosis have been seen on very rare occasions. Thrombophlebitis 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. Please refer to the corresponding section on intravascular use in Section 4.8 Adverse Effects (Undesirable Effects) for full information on anaphylactoid reactions.

### **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

Australia: <http://www.tga.gov.au/reporting-problems>

New Zealand: <https://nzphvc.otago.ac.nz/reporting/>

## 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, haemodialysis can be used to eliminate the bulk of the contrast medium from the patient's system.

For information on the management of overdose, contact:

Australia: The Poison Information Centre on 131126 (Australia)

New Zealand: The National Poisons Centre on 0800 POISON (0800 764766)

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 PHARMACODYNAMIC PROPERTIES

#### Mechanism of action

No data available

#### Clinical trials

No data available

### 5.2 PHARMAOKINETIC 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

One day after first opening the container and without withdrawal of any contrast medium.

### 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 are marketed in Australia or New Zealand.

## 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

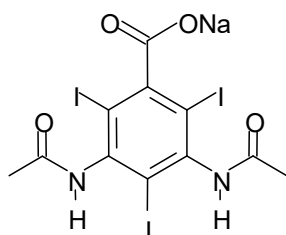
In Australia or New Zealand, any unused medicine or waste material should be disposed of in accordance with local requirements.

## 6.7 PHYSICOCHEMICAL PROPERTIES

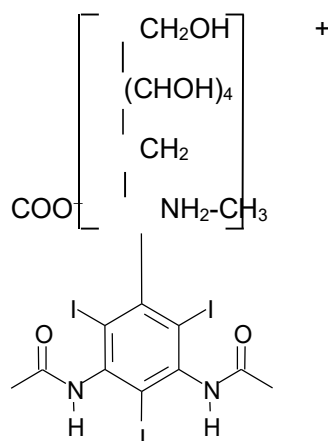
	Molecular formula	Chemical name	Molecular weight	Solubility in water
Sodium amidotrizoate (CAS No. 737-31-5)	C <sub>11</sub> H <sub>8</sub> I <sub>3</sub> N <sub>2</sub> NaO <sub>4</sub>	Sodium 3,5-diacetamido-2,4,6-triodobenzoate	635.90	Freely soluble
Amidotrizoate meglumine (CAS No. 131-49-7)	C <sub>18</sub> H <sub>26</sub> I <sub>3</sub> N <sub>3</sub> O <sub>9</sub>	N-methylglucamine 3,5-diacetamido-2,4,6-triodobenzoate	809.13	Freely soluble

### Chemical structure

Sodium amidotrizoate



Amidotrizoate meglumine



## Physico-chemical properties

<b>Urografin</b>	<b>30%</b>	<b>76%</b>
Iodine concentration (mg/mL)	146	370
Iodine content (g) per ampoule of 10mL bottle of 50mL bottle of 100mL bottle of 250mL	1.46 - - 36.5	- 18.5 37.0 -
Contrast medium concentration (mg/mL)	300	760
Contrast medium content (g) per ampoule of 10mL bottle of 50mL bottle of 100mL bottle of 250mL	3.0 - - 75.0	- 38.0 76.0 -
Viscosity (mPa•s or cP) at 20°C at 37°C	2.2 1.4	18.5 8.9
Osmotic pressure at 37°C (MPa) (atm)	1.78 17.6	5.4 53.3
Osmolality at 37°C (osm/kg H <sub>2</sub> O)	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)**

Australia: Not Scheduled

New Zealand: General Sales Medicine

## **8 SPONSOR**

Bayer Australia Ltd  
ABN 22 000 138 714  
875 Pacific Highway  
PYMBLE NSW 2073  
[www.bayer.com.au](http://www.bayer.com.au)

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Hillcrest North Shore  
Auckland 0627  
Free phone 0800 233 988

## 9 DATE OF FIRST APPROVAL

17 September 2007

Ref: Urografin Corporate Core Text dated 24 February 2003

## 10 DATE OF REVISION

29 November 2018

Ref: TGA approved Urografin Product Information text dated 14 June 2018

### *Summary table of changes*

<b>Section changed</b>	<b>Summary of new information</b>
All sections	Reformatted into the SmPC format. Minor editorial changes
4.4	Addition of warning to not administer antihistamines or glucocorticoids with contrast media Addition of warning of potential interaction with biguanides when administered intravascularly 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.