Urografin

Contrast media for urography and angiography

Important information, please read carefully!

Composition

1 ml Urografin 76% contains 0.1 g sodium amidotrizoate and 0.66 g meglumine amidotrizoate (sodium diatrizoate and meglumine diatrizoate) in aqueous solution.

Urografin	76%
Iodine concentration (mg/ml)	370
Iodine content (g) per Ampoule of 20 ml	7.4
Contrast medium concentration (mg/ml)	760
Contrast medium content (g) per Ampoule of 20 ml	15.2
Viscosity (mPa. s or cP) at 20°C at 37°C	 18.5 8.9
Osmotic pressure at 37°C (MPa) (atm)	 5.40 53.3
Osmolality at 37°C (osm/kg H2O)	2.10

Indications

Intravenous and retrograde urography.

Also for all angiographic examinations as well as for amniography, arthography, intraoperative cholangiography, 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.

Dosage and administration

- General information

Vials containing contrast medium solutions are not intended for 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).

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.

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

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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.

Ionic iodinated contrast media inhibit blood coagulation, in vitro, more than non-ionic contrast media. Nevertheless medical personnel performing vascular catheterization procedures should pay meticulous attention to the angiographic technique and catheter flushing with physiological saline solution so as to minimize the risk of procedure-related thrombosis and embolism.

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.

Should diagnostic clarification necessitate several high single doses, the organism should be given the opportunity 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 300 ml contrast medium are required for a single examination.

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

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.

➢ Intravenous urography.

- Injection

Urografin 60% and 76% are equally well suited 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 20 - 30 minutes is recommended.

- Dosage

Adults
The dose is 20 ml Urografin 76% or 50 ml Urografin 60%. 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% :

up to 1 year	7 - 10 ml
1 - 2 years	10 - 12 ml
2 - 6 years	12 - 15 ml
6 - 12 years	15 - 20 ml
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. The earlier time should be chosen for younger patients and the later time for older patients.

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

Insufficient contrast can necessitate later films.

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- Infusion

Adults and adolescents
1 bottle of 100 ml
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.

Compression is inadvisable during the infusion of large amounts of contrast medium, 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

An approximately 30% solution, obtained by diluting the Urografin 60% solution with about the same amount of water for injection, is generally sufficient for retrograde urography. It is advisable to warm the contrast medium to body temperature to avoid low-temperature stimulus and resultant ureteral spasms.

The undiluted Urografin 60% 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 is also suitable for angiographic examinations. The 76% solution is preferred for those angiographic examinations 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.

The 200 ml bottle of Urografin 76% is particularly suitable for the special indication ventriculocoronarography.

➢ Consult special literature for further indications.

Contraindication

Manifest hypertiroidism, decompensated cardiac insufficiency.

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

Please note

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.

Experience shows that patients with an allergic disposition suffer more frequently than others from hypersensitivity reactions. In such cases, some examiners administer e.g. antihistamines and/or corticoids prophylactically. However, contrast media and prophylactic agents should not be administered mixed together.

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.

It has not yet been demonstrated that Urografin can be safely used 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.

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

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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.

Special warnings and special precautions for use

For all indications
The following warnings and precautions apply to any mode of administration, however, the risks mentioned are higher in intravascular administration.

- Thyroid dysfunction

Particularly careful risk-benefit assessment is required in patients with known or suspected hyperthyroidism or goiter, as iodinated contrast media may interfere with thyroid function, aggravate or induce hyperthyroidism and thyreotoxic 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, specially 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.

Side Effects

Side effects in association with the use of iodinated intravascular contrast media are usually of a mild to moderate and temporary nature, although severe and life-threatening reactions as well as deaths 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 sensation of warmth or nausea can usually be alleviated quickly by reducing the rate of administration or interrupting the administration briefly.

Other symptoms which may occur are:
Chills, fever, sweating, headache, dizziness, blanching, weakness, gagging and a feeling of suffocation, gasping, a rise or fall of blood pressure, itching, urticaria, other kinds of skin eruption, oedema, cramp, tremor, sneezing and lacrimation. 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. 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 ventilator should be ready to hand (cf. "Suggestions for the treatment of contrast medium incidents"). 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.

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

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 neurological complications such as coma, temporary states of confusion and somnolence, transient pareses, disturbed vision or slack facial mcrscles and - particulaly in epileptics and patints with focal brain damage - epileptic fits. Very rarely, the induction of fits in these patients has been described on intravenous administration of the contrast medium as well.

Temporary renal failure may occur in rare cases.

Delayed reactions can occasionally occur.

Suggestions for the treatment of contrast medium incidents

It is of decisive importance for prompt action in the event of contrast medium incidents to have all drugs and instruments for emergency therapy readily available and to be familiar with the practice of emergency measures.

The following procedure is recommended:

1. Intravenous injection of a high-dosed water soluble corticoid, e.g. 6α-methylprednisolone-hemisuccinate sodium at the following dosage: in all cases immediately 500 mg (children under 4 years 250 mg) over a period of 2- 3 minutes; in life-threatening conditions increase the dose over a period of another 3 - 5 minutes to 30 mg/kg body weight (example: approx. 2,000 mg for 70 kg body weight).
   Leave the cannula or catheter in the vein to maintain access to the vascular system. Some doctors prefer early volume replacement (cf. "Circulatory insufficiency and shock") and implement this before or when administering the corticoid

2. Administer oxygen, if necessary carry out positive-pressure oxygen respiration.
   Further measures will depend on the most prominent symptoms and the condition of the patient. The dosages of the specified preparations are valid only for adults and must be reduced for children in accordance with their age.

- Circulatory insufficiency and shock: immediately place the patient in the shock position (head down, legs and arms high). Slow i.v. injection of peripheral vasopressors, volume replacement with blood substitutes. Infuse noradrenaline, 5 mg in 500 ml liquid (e.g. isotonic sodium chloride solution), dosage according to effect, about 10 - 20 drops/minute. Continously check pulse and blood pressure.

- Cardiac arrest (asystole): energetic, quickly slackening pressure on the thoracic wall over the middle of the sternum; if unsuccessful, immediately extrathoracic cardiac massage and artificial respiration (mouth to mouth, positive-pressure oxygen respiration, where possible endotracheal intubation). 0.5 mg orciprenaline intracardially, cardiac pacemaker. After the return of spontaneous but weak cardiac contractions calcium gluconate 0.5- 1 g i.v. (5- 10 ml of a 10% solution). Beware of using calcium in patients receiving cardiac glycoside.

- Ventricular fibrillation: immediately extrathoracic cardiac massage and artificial respiration. Defibrillation with a cardiac defibrillator, repeat if necessary. If unsuccessful or no defibrillator is available, procainamide 0. 5 g intracardially. Sodium bicarbonate solution i.v., e.g. 50 ml of an 8.4% solution (1 mval/ml) every 5 - 10 minutes, to combat the hypoxaemic acidosis which always develops in the event of cardiac arrest or ventricular fibrillation. Check blood pH.

- Pulmonary oedema: phlebostasis with a blood pressure cuff, in adults perhaps phlebotomy. A quick-acting diuretic i.v. and, in adults, infusion of 100 ml of a 40% glucose solution for osmodiuresis. If patient is not yet digitalized, rapid saturation with a suitable cardiac glycoside, e.g. in adults 0.125- 0.25 mg ouabain (strophanthin) i.v. (beware in cases of mitral stenosis). Positive-pressure respiration, but not in patients with shock.

- Cerebral symptoms: in the event of restlessness a tranqulizer (e.g. diazepam) i.m. or slowly i.v.; in severe states of exitation neuroleptics, possibly combined with promethazine 50 mg, intragluteally. For cerebro-organic convulsions phenobarbital 0.2 - 0.4 g i.m., for severe convulsive states (epileptic status) i.v. injection of a short- acting anaesthetic.

- Allergic symptoms: for severe urticarua, injection of an antihistamine, possibly also a calcium preparation. in addition to corticoids (caution must be exercised with calcium in patients receiving cardiac glycosides); for asthmatic attacks a theophylline preparation very slowly i.v.; if necessary orciprenaline 0.5 mg very slowly i.v.; in oedema of the glottis an antihistamine (e.g. promethazine50 mg) slowly i.v. Tracheotomy may be necessary if the upper respiratory tract is obstructred.

Presentation

Box. 10 Ampoules @ 20 ml

Reg. No.: XXXXXXXXXXXX
Store all drugs properly and keep them out of reach of children.
Protect from light and secondary X-rays
Store below 30°C

Harus dengan resep dokter

Manufactured by: Berlimed S.A. Madrid-Spain

Imported by:
PT. Bayer Indonesia, Depok-Indonesia

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