Urografin (sodium amidotrizoate and meglumine amidotrizoate)

Urografin® (sodium amidotrizoate and meglumine amidotrizoate) Prescribing Information

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 1ml of Urografin 150 and Urografin 150 for infusion contains 40mg sodium amidotrizoate (sodium diatrizoate) and 260mg meglumine amidotrizoate (meglumine diatrizoate). **Indication(s):** X-ray contrast medium for the delineation of the vascular and renal systems. **Posology & method of administration:** Suggested doses for investigations are: ***Adults*:** Drip infusion urography 2–4 ml/kg body weight up to 250 ml, Retrograde urography 5–10 ml, Cystography up to 500 ml. ***Children and neonates*:** Drip-infusion urography: Dosage of Urografin 150 should not exceed 4ml/kg body weight. ***General Information:*** Experience shows that contrast medium is tolerated better if it is warmed to body temperature. If patients with cardiac insufficiency are given 100ml or more, an injection time of at least 20 - 30 minutes is recommended. Excipient with known effect: Sodium calcium edetate. **Contra-indications:** Proven or suspected hypersensitivity to iodine-containing contrast media; uncontrolled thyrotoxicosis, decompensated cardiac insufficiency; hysterosalpingography must not be carried out during pregnancy or in patients with acute inflammatory conditions in the pelvic cavity. **Warnings & precautions:** Carefully consider use of X-ray with contrast media in patients with severe impairment of hepatic or renal function, cerebral arteriosclerosis, epileptic conditions, diabetes mellitus requiring drug treatment and/or associated with diabetic complications, pulmonary emphysema, poor general health, latent hyperthyroidism, multiple myeloma or benign nodular goitre. Patients with a history of allergy, atopy, bronchial asthma, endogenous eczema, cardiac or circulatory insufficiency or a previous adverse reaction with any contrast medium may be at higher risk from developing anaphylaxis or cardiovascular collapse. Consider use of low osmolar radiocontrast media in these patients. The patient should be recumbent during the administration of Urografin and kept under close observation for at least 30 minutes after administration. Patients with a labile circulation should be brought to the X-ray machine sitting or lying down. Particular caution should be exercised in people with allergies who have previously tolerated an injectable iodine-containing contrast medium without any complication due to possible sensitisation. As with any contrast medium, the possibility of hypersensitivity must always be considered. If marked side-effects or suspected allergic reactions occur during injection and do not disappear, or get worse, when the injection is briefly interrupted, it is probable that the patient is hypersensitive and the investigation must be abandoned. Minor symptoms such as itching of the skin, sneezing, violent yawns, tickling in the throat, hoarseness or attacks of coughing may be early signs of a severe reaction. Ionic iodinated contrast media inhibit blood coagulation in vitro more than non-ionic contrast media. Pay meticulous attention to angiographic technique and flush intravascular catheters frequently to minimise the risk of procedure-related thrombosis and embolisation. In patients with multiple myeloma, diabetes mellitus requiring drug treatment, polyuria, oliguria, gout or marasmus, and in infants or young children, do not restrict fluid supply. Correct disturbances of electrolytes or water balance before administration. In patients with phaeochromocytoma, premedication with an alpha-blocker is recommended, because of the risk of hypertensive crisis. 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. Pronounced states of excitement, anxiety and pain can be the cause of side effects or intensify contrast medium-related reactions. Not suitable for myelography. Urografin contains 362.50 mg of sodium in each dose (250 ml), equivalent to 18.1% of the WHO recommended maximum daily intake of 2 g sodium for an adult. **Interactions:** Stop biguanides 48 hours prior to contrast medium examination as a precaution against lactic acidosis. Reinstate only after adequate renal function has been regained. Hypersensitivity reactions can be aggravated in patients on beta-blockers. Prevalence of delayed reactions (e.g. fever, rash, flu-like symptoms, joint pain and pruritus) is higher in patients who have received interleukin. Pregnancy & lactation: X-ray examinations should if possible be avoided during pregnancy. An examination with a contrast medium during pregnancy should be carried out only if considered absolutely necessary. Renally eliminated contrast media such as Urografin enter the breast milk in only very small amounts. Limited data suggest that the risk to the suckling infant of administering salts of diatrizoic acid to its mother is low. Effects on ability to drive and use machines: Patients should avoid driving/ operating machinery for the first 24 hours. Undesirable effects: Mild symptoms such as heat or nausea, occur very seldom and disappear rapidly when the injection is slowed down or interrupted. Transient pain may occur in particular during peripheral vascular examinations. 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; lacrimation. These reactions can occur irrespective of the dose and the mode of administration and may be the first signs of incipient shock. Administration of the contrast medium must be discontinued immediately and, if necessary, specific therapy instituted intravenously. It is advisable to use a flexible indwelling cannula for intravenous contrast medium administration. Very rarely, severe or even life-threatening side-effects such as severe hypotension and collapse, circulatory failure, ventricular fibrillation, cardiac arrest, pulmonary oedema, anaphylactic shock or other allergic manifestations, convulsions, or other cerebral symptoms may occur. In some cases these have proved fatal. Appropriate drugs, an endotracheal tube and a ventilator should be ready to hand. Hypersensitivity reactions occur more frequently in patients with an allergic disposition. Paravascular administration of the contrast medium rarely leads to severe tissue reactions. Delayed reactions can occasionally occur. Neurological complications such as coma, temporary states of confusion and somnolence, transient paresis, disturbed vision or facial muscle paresis and epileptic fits may occur after cerebral angiography and other procedures in which the contrast medium reaches the brain with the arterial blood. In very rare cases the induction of fits has been observed after intravenous administration of Urografin in epileptics and patients with focal brain damage; however, a causal relationship seems to be questionable. Temporary renal failure may occur in rare cases. **Overdose:** Acute symptoms of poisoning are unlikely with intravascular administration. Following inadvertent overdosage or in greatly impaired renal function, the contrast medium may be removed by dialysis, and the balance of water and electrolytes should be corrected. Acute toxicity studies do not suggest a risk of acute intoxication. **Incompatibilities:** Do not mix contrast media and prophylactic antihistamine or corticoid agents. **Special Precautions for Storage:** Protect from light and X-rays. **Legal Category:** POM **Package Quantities & Basic NHS Costs:** Urografin 150: Ampoules: 10 x 10ml £ 29.30 10 x 20ml £ 48.67 Urografin 150 for infusion: Bottles: 1 x 250ml £21.20 1 x 500ml £41.60 **MA Number(s):** Urografin 150 00010/0569, Urografin 150 for infusion 00010/0568 **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** Jan 2019

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Bayer plc.
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