Prescribing information on Bayer Contrast Media products available in the UK

Gadovist® (gadobutrol)

Gadovist® 1.0 mmol/ml solution for injection (gadobutrol) and Gadovist® 1.0 mmol/ml solution for injection pre-filled syringe/cartridge (gadobutrol) Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing) **Presentation:** Glass vials containing 15ml, or glass prefilled syringes containing 5ml, 7.5ml or 10ml, of gadobutrol 1.0 mmol/ml solution for injection (604.72 mg gadobutrol/ml). **Indications:** ***Adults and children of all ages (including term neonates):*** Contrast enhancement in cranial and spinal MRI; MRI of liver and kidneys if suspicion or evidence of focal lesions; MRI of pathologies of the whole body and in magnetic resonance angiography (CE-MRA). Use only when diagnostic information is essential and not available with unenhanced MRI. **Posology and method of administration:** Gadovist should only be administered by healthcare professionals experienced in the field of clinical MRI practice. This medicinal product is for intravenous administration only. Give required dose intravenously as bolus injection. Patient should be recumbent during administration. MRI can start immediately after injection. Optimal signal enhancement usually occurs during arterial first pass for CE-MRA and within 15 minutes of injection for CNS indications. Particularly suitable for T1-weighted scanning sequences. Observe patient for at least 30 minutes after administration. Intended for single use only. Contrast medium not used in one examination must be discarded. Visually inspect before use; do not use in case of severe discolouration, occurrence of particulate matter or defective container. *Vials*: draw up into syringe immediately before use; never pierce rubber stopper more than once. *Pre-filled syringe:* prepare immediately before administration. Use the lowest dose that provides sufficient enhancement for diagnostic purposes. The dose should be calculated based on the patient's body weight, and should not exceed the recommended dose per kg of body weight detailed below. **CNS indications:** ***Adults*****:** 0.1mmol/kg body weight (BW) (equivalent to 0.1ml/kg BW). A further injection of 0.2ml/kg BW may be given within 30 minutes of first injection. **Whole Body MRI (except MRA):** ***Adults:*** 0.1 ml/kg BW. **CE-MRA:** ***Adults*****:** Imaging of 1 field of view (FOV): 7.5ml for BW below 75 kg, 10ml for BW of 75 kg and higher (corresponding to 0.1-0.15 mmol/kg BW). Imaging of >1 FOV: 15ml for BW below 75 kg, 20ml for BW of 75 kg and higher (corresponding to 0.2-0.3 mmol/kg BW). ***Renal impairment:*** Only use in patients with severe renal impairment (GFR < 30ml/min/1.73m2), and in patients in perioperative liver transplantation period after careful risk/ benefit assessment and if diagnostic information is essential and not available with non-contrast enhanced MRI. If it is necessary to use Gadovist, dose should not exceed 0.1 mmol/kg BW. Do not use more than one dose per scan. Do not repeat the dose for at least 7 days. ***Paediatric population:*** For children of all ages (including term neonates): 0.1mmol/ kg BW (equivalent to 0.1ml/kg BW) for all indications. ***Neonates up to 4 weeks of age and infants up to 1 year of age:*** Due to immature renal function Gadovist should only be used in these patients after careful consideration at a dose not exceeding 0.1 mmol/kg body weight. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, Gadovist injections should not be repeated unless the interval between injections is at least 7 days. ***Elderly (65+ years):*** No dose adjustment necessary but exercise caution. **Contra-indications:** Hypersensitivity to ingredients. **Warnings and precautions:** If injecting into veins with a small lumen, adverse effects such as reddening or swelling may occur. As with other intravenous contrast agents, Gadovist can be associated with anaphylactoid/hypersensitivity or other idiosyncratic reactions, characterised by cardiovascular, respiratory or cutaneous manifestations ranging to severe reactions including shock. In general, patients with cardiovascular disease are more susceptible to serious or fatal outcomes of severe hypersensitivity reactions. Risk of hypersensitivity reactions may be higher in case of previous reaction to contrast media, history of bronchial asthma and allergic disorders. In patients with an allergic disposition, carefully evaluate the risk-benefit ratio. Most reactions occur within half an hour of administration. Medication for the treatment of hypersensitivity reactions as well as preparedness for the institution of emergency measures are necessary. In rare cases, delayed anaphylactoid reactions (after hours to days) have been observed. Prior to administration, it is recommended to screen all patients for renal dysfunction by laboratory testing. Nephrogenic systemic fibrosis (NSF) has been reported with some gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30ml/min/1.73m2). Patients undergoing liver transplantation are at particular risk since the incidence of acute renal failure is high in this group. Only use in patients with severe renal impairment and those in the perioperative liver transplantation period after careful risk/benefit assessment and if the diagnostic information is essential and not available with non-contrast enhanced MRI. Haemodialysis shortly after Gadovist administration may be useful in removing Gadovist from the body. As renal clearance may be impaired in the elderly, it is particularly important to screen patients aged 65+ years for renal dysfunction. Use with caution in patients with a low seizure threshold. **Fertility, pregnancy and lactation:** Animal studies do not indicate impairment of fertility, but have shown reproductive toxicity at repeated high doses. Do not use during pregnancy unless the clinical condition of the woman requires the use of gadobutrol. Gadolinium containing contrast agents are excreted into breast milk in very small amounts. At clinical doses no effects on the infant are anticipated. **Undesirable effects:** Most undesirable effects are of mild to moderate intensity. ***Common:*** Nausea, headache. ***Uncommon:*** Hypersensitivity/anaphylactoid reaction* (e.g. anaphylactoid shock*, circulatory collapse*, respiratory arrest*, pulmonary oedema*, bronchospasm, cyanosis, oropharyngeal swelling*, laryngeal oedema, hypotension*, blood pressure increased, chest pain, urticaria, face oedema, angioedema, conjunctivitis, eyelid oedema, flushing, hyperhidrosis, cough, sneezing, burning sensation, pallor), dyspnoea*. ***Rare:*** Loss of consciousness*, convulsion. ***Not known:*** Cardiac arrest*, Nephrogenic systemic fibrosis (NSF) (isolated cases). Patients with an allergic disposition more frequently suffer from hypersensitivity reactions. Fluctuations of renal function parameters including increases of serum creatinine have been observed. *There have been reports of life threatening and/or fatal outcomes from this adverse drug reaction (ADR). Prescribers should consult the SmPC in relation to other side effects. **Overdose:** No signs of intoxication from an overdose have so far been reported during clinical use. In case of overdose, perform cardiovascular monitoring (including ECG) and control renal function as a measure of precaution. In patients with renal insufficiency, Gadovist can be removed by haemodialysis. After 3 haemodialysis sessions approx. 98% of agent is removed from the body. There is no evidence that haemodialysis is suitable for prevention of NSF. **Incompatibilities:** Do not mix Gadovist with other medicinal products. **Legal category:** POM **Basic NHS Price:** 1 x 15ml vial £101.26, 1 x 7.5ml pre-filled syringe £50.63, 5 x 5 ml pre-filled syringes £168.77, 5 x 10ml prefilled syringes £337.54. MA Numbers: PL 00010/0535 (vials), PL 00010/0536 (prefilled syringes) **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** February 2018.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
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Primovist® (gadoxetate disodium)

Primovist® 0.25 mmol/ml, solution for injection, prefilled syringe (gadoxetate disodium) Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Each ml solution for injection contains 181.43mg/ml gadoxetate disodium. **Indication(s):** Detection of focal liver lesions and providing information on the character of lesions in T1-weighted magnetic resonance imaging (MRI). Use only when diagnostic information is essential and not available with unenhanced MRI and when delayed phase imaging is required. For diagnostic use by intravenous administration only. **Posology & method of administration:** Observe usual safety precautions for MRI (e.g. exclude cardiac pacemakers and ferromagnetic implants). Administer dose undiluted as an intravenous bolus injection at a flow rate of about 2ml/sec. After injection, flush cannula/line with 0.9% saline. Observe patients for at least 30 minutes after the injection. Use the lowest dose that provides sufficient enhancement for diagnostic purposes. The dose should be calculated based on the patient's body weight and should not exceed the recommended dose per kg of body weight detailed below. Recommended doses are: ***Adults:*** 0.1ml/kg body weight. ***Impaired renal function:*** Use of Primovist should be avoided in patients with severe renal impairment (GFR <30ml/min/1.73m2) and in patients in the perioperative liver transplantation period unless the diagnostic information is essential and not available with non-contrast enhanced MRI. If use cannot be avoided, dose should not exceed 0.025mmol/kg body weight. Do not use more than one dose per scan. Do not repeat the dose for at least 7 days. ***Paediatric population:*** The safety and efficacy of Primovist have not been established in patients under 18 years old. ***Patients with hepatic impairment:*** No dose adjustment necessary. ***Elderly population (≥65yrs):*** No dose adjustment necessary. Exercise caution. **Contra-indications:** Hypersensitivity to active substance or to any excipients**. Warnings & precautions:** It is recommended to screen all patients for renal dysfunction by obtaining laboratory tests, particularly patients over 65 yrs. Nephrogenic systemic fibrosis (NSF) has been reported with some gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR<30ml/min/1.73m2); Patients undergoing liver transplantation are at particular risk since incidence of acute renal failure is high in this group. Use should be avoided in patients with severe renal impairment and in patients in perioperative liver transplantation period unless diagnostic information is essential and not available with non-contrast enhanced MRI. Haemodialysis shortly after Primovist administration may be useful at removing Primovist from the body. There is no evidence to support initiation of haemodialysis for prevention or treatment of NSF in patients not already undergoing haemodialysis. Use with caution in patients: with severe cardiovascular problems; with, or with a family history of, congenital long QT syndrome; with drugs known to prolong cardiac repolarisation, particularly in patients with previous arrhythmias. Should not be used in patients with uncorrected hypokalaemia. Primovist may cause transient QT prolongation. Allergy-like reactions, including shock, reported rarely. Patients with a history of allergic disorders or bronchial asthma or who have previously reacted to contrast media are at higher risk of hypersensitivity reactions. Most reactions occur within 30 minutes of administration but rarely delayed reactions may occur after hours to days. Appropriate drugs and instruments for treatment of hypersensitivity must be readily available. Hypersensitivity reactions can be more intense in patients on beta-blockers, particularly in patients with asthma. Patients taking beta-blockers who experience hypersensitivity may be resistant to treatment effects of beta-agonists. If hypersensitivity reactions occur, stop injection immediately. Do not administer intramuscularly due to risk of local intolerance reactions including focal necrosis. After administration of gadoxetate disodium, gadolinium can be retained in the brain and in other body tissues (bones, liver, kidneys, skin) and can cause dosedependent increases in T1-weighted signal intensity in the brain, particularly in the dentate nucleus, globus pallidus, and thalamus. Clinical consequences are unknown. The possible diagnostic advantages of using gadoxetate disodium in patients requiring repeated scans should be weighed against the potential for deposition of gadolinium in the brain and other tissues. Consider the sodium content (11.7mg/ml) for patients on controlled sodium diet. **Interactions:** Potent OATP inhibitors could cause drug interactions reducing the hepatic contrast effect. No clinical data exists to support this theory. Elevated levels of bilirubin or ferritin can reduce the hepatic contrast effect of Primovist. Primovist may interfere with serum iron determinations for up to 24 hours after administration**. Pregnancy & lactation:** There are no data from use in pregnant women. Animal studies have shown reproductive toxicity at repeated high doses. Should not be used in pregnancy unless clinical condition of the woman requires the use of Primovist. Gd-containing contrast agents are excreted into breast milk in very small amounts. Continuing or discontinuing breast feeding for 24 hours after administration should be at discretion of the doctor and lactating mother. Animal studies did not indicate impairment of fertility. **Undesirable effects:** (please refer to the Contra-indications and the Warnings and Precautions sections). Usually mild to moderate and transient. The most serious adverse reaction is anaphylactoid shock. Delayed allergoid reactions (hours later up to several days) are rare. *Common* - headache, nausea. *Uncommon* – vertigo; paraesthesia; increased blood pressure; dyspnoea*; respiratory distress; rash; back pain; chest pain, injection site reactions; fatigue. *Rare* - akathisia; bundle branch block; palpitation; maculopapular rash; malaise. Additionally, altered laboratory tests and transient QT prolongation were reported. *Frequency not known* – Hypersensitivity / anaphylactoid reaction (including shock*, pharyngolaryngeal oedema); tachycardia and restlessness. *Life-threatening and/or fatal cases have been reported post marketing. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** In excessive inadvertent overdose, monitor patient including cardiac monitoring (for possible induction of QT prolongation); remove by haemodialysis. However there is no evidence that haemodialysis is suitable for prevention of nephrogenic systemic fibrosis (NSF). **Incompatibilities:** Do not mix Primovist with other medicinal products. **Legal Category:** POM **Package Quantities & Basic NHS Costs:** 1 x 10ml prefilled syringe £96.10. **MA number:** PL 00010/0555. **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** February 2018.

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Magnevist® 2mmol (gadopentic acid, dimeglumine salt)

Magnevist® 2mmol/l solution for injection (gadopentetic acid, dimeglumine salt) Prescribing Information
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Glass pre-filled syringes containing 20ml of gadopentetic acid, dimeglumine salt (1.876 mg/ml). **Indications:** Contrast enhancement in direct magnetic resonance arthrography. For diagnostic use by intraarticular administration only. Use only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI) and when another authorised product cannot be used. **Posology and method of administration (at 0.2 to 1.5 Tesla):** Observe usual precautions for MRI (e.g. exclusion of cardiac pacemakers and other ferro-magnetic objects including vascular clips etc). Give dose via intraarticular injection under strict aseptic technique and with patient lying or sitting. Contrast-enhanced MRI can start immediately afterwards. Observe patient for at least 30 minutes after administration. Use the lowest dose that provides sufficient enhancement for diagnostic purposes. ***Adults:*** In general, for all joints up to 20ml (knee joint up to 50ml) is sufficient. Inject a volume leading to slight distension of the joint capsule, until discrete resistance is felt and/or the patient feels a mild pressure. ***Paediatric population:*** Safety and efficacy of Magnevist 2mmol/l in children aged up to 18 years has not yet been established. No data are available. Not recommended until further data become available. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Warnings and precautions:** Use strict aseptic technique to prevent infection. Use fluoroscopic control to ensure proper needle placement and prevent extracapsular injection. Do not exert undue pressure during injection and avoid infected joints. ***Hypersensitivity:*** Severe systemic hypersensitivity reactions cannot be excluded. Mild angioedema, conjunctivitis, coughing, pruritus, rhinitis, sneezing and urticaria may be first signs of incipient state of shock, irrespective of amount administered or method of administration. Delayed reactions (after hours or days) may occur. Post-procedure observation is recommended. Appropriate drugs and instruments must be readily available for treatment of hypersensitivity reactions. The risk of hypersensitivity reaction is higher in patients with previous reaction to contrast media, a history of bronchial asthma or allergic disorders. In patients with an allergic disposition, carefully evaluate risk-benefit ratio. After intravenous administration of gadopentetic acid, dimeglumine salt, gadolinium can be retained in the brain and in other body tissues (bones, liver, kidneys, skin) and can cause dose-dependent increases in T1-weighted signal intensity in the brain, particularly in the dentate nucleus, globus pallidus, and thalamus. Clinical consequences are unknown. Retention of gadolinium in the brain has not been identified for intra-articular administration. The possible diagnostic advantages of using gadopentetic acid, dimeglumine salt in patients requiring repeated scans should be weighed against the potential for deposition of gadolinium in the brain and other tissues. Magnevist 2mmol/l contains sodium. **Interactions:** Do not mix Magnevist 2mmol/l with iodinated contrast media since this will reduce efficacy. **Pregnancy and lactation:** No clinical data on exposed pregnancies are available. Exercise caution with use in pregnant women. No data exist concerning intraarticular administration in lactating women. After intravascular use a max. of 0.04% of IV administered dose enters breast milk and is considered unlikely to cause harm to infants. **Effects on ability to drive and use machines:** No effects of Magnevist 2mmol/l on driving ability or use of machinery expected but the joint effusion may affect driving due to a limited joint mobility. **Undesirable effects:** Frequencies are from clinical trial data. Undesirable effects listed here were classified by investigators as drug-related. Adverse reactions are usually mild to moderate intensity. ***Common*****:** Injection site pain/ pressure sensation (joint). ***Uncommon:*** Headache, dizziness, nausea. ***Rare:*** Vasovagal reaction, vomiting. ***Immune system disorders/ hypersensitivity/ allergic reaction:*** Systemic hypersensitivity may occur rarely as skin reactions. Severe hypersensitivity reactions cannot be excluded. ***General disorders and administration site conditions:*** injection into the joint is commonly associated with transientdiscomfort.
Severe pain may often result from undue use of pressure or injection of large volumes. Other adverse reactions seen with i.v. injections of gadolinium chelates have not been reported with Magnevist 2mmol/l due to the low dose and topical administration. Prescribers should consult the SmPC in relation to the side effects. **Overdose:** No signs of intoxication secondary to overdose have been reported. **Legal Category:** POM Package **Quantities and Basic NHS Costs:** 1 x 20ml pre-filled syringe £29.05 **MA Number:** PL 00010/0544 **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, UK. **Telephone**: 0118 206 3000 **Date of preparation:** January 2019.

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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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Gastrografin® (sodium amidotrizoate and meglumine amidotrizoate)

Gastrografin gastroenteral solution (sodium amidotrizoate and meglumine amidotrizoate) Prescribing Information
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 100ml bottle of aqueous solution for enteral use; 1ml solution contains: 100mg sodium amidotrizoate (sodium diatrizoate) and 660mg meglumine amidotrizoate (meglumine diatrizoate). **Indication(s):** For diagnostic use by oral or rectal administration only. Gastrografin is for the radiological investigation of the gastrointestinal tract (also in combination with barium sulphate). Gastrografin may be of particular value in the following instances: (1) Suspected partial or complete stenosis, (2) Acute haemorrhage, (3) Threatening perforation (peptic ulcer, diverticulum), (4) Other acute conditions which are likely to require surgery, (5) After resection of the stomach or intestine (danger of perforation or leak), (6) Megacolon, (7) Visualisation of a foreign body or tumour before endoscopy, (8) Visualisation of a gastrointestinal fistula, (9) Before endoscopy. Further indications: Early diagnosis of a radiologically undetectable perforation or anastomotic defect in the oesophagus. The treatment of uncomplicated meconium ileus. Computerised tomography in the abdominal region. **Posology & method of administration: Oral administration:** ***Adults & children of 10 years of age or over:*** Visualisation of the stomach: 60 ml. Follow-through examination of the gastrointestinal tract: a maximum of 100 ml **Computerised tomography:** ***Adults & children of 10 years of age or over:*** 0.5 to 1.5 litres of approx. 3% solution of Gastrografin in water (30 ml/litre). ***Elderly or cachectic patients***: Dilution with an equal volume of water is recommended. ***Children up to 10 years of age:*** 15-30 ml (can be diluted with twice its volume of water). ***Infants & young children:*** 15-30 ml (diluted with three times its volume of water). **Rectal administration:** ***Adults:*** Up to 500 ml Gastrografin dilution (diluted with 3-4 times its volume of water). ***Children over 5 years of age:*** up to 500ml Gastrografin dilution (diluted with 4-5 times its volume of water); ***Children up to 5 years of age:*** up to 500ml Gastrografin dilution (diluted with 5 times its volume of water). **Therapy of uncomplicated meconium ileus**: Gastrografin can be given by enema for non-operative treatment of uncomplicated meconium ileus. The procedure must be carried out slowly and only under fluoroscopic control. Injection should stop as soon as Gastrografin is seen to enter the ileum. Intravenous fluids must be set up before the enema is given, and infused as required. If the Gastrografin is not expelled during the first hour after removal of the rectal catheter, an X-ray should be taken to ensure that overdistension of the bowel as a result of the high osmolarity of Gastrografin has not occurred. **Gastrografin and Barium Sulphate: Oral and rectal administration**. ***Adults***: 30 ml Gastrografin plus the usual dose of barium should be adequate. ***Children from 5-10 years of age:*** 10 ml Gastrografin to 100ml barium sulphate suspension. ***Children up to 5 years of age:*** 2-5 ml Gastrografin to 100 ml barium sulphate suspension. The portion of Gastrografin in the suspension may be further increased in cases of pylorospasm or pyloric stenosis. This does not affect the contrast. For the early diagnosis of a perforation or investigation of an anastomosis in the oesophagus or gastrointestinal tract, the patient should drink up to 100 ml Gastrografin. After 30-60 minutes (later, if the defect is suspected of being in the distal gut), a urine specimen should be taken and 5 ml mixed with 5 drops of concentrated hydrochloric acid. The contrast medium which has undergone renal excretion will appear within two hours as a typical crystal formation in the precipitate. **Contra-indications:** Hypersensitivity to iodine-containing contrast media. Manifest hyperthyroidism. Gastrografin must not be administered undiluted in patients with low plasma volume, e.g. newborns, infants, children and in dehydrated patients. Gastrografin must not be administered undiluted in patients with suspected possibility of aspiration or broncho-oesophageal fistula, since hyperosmolarity may cause acute pulmonary oedema, chemical pneumonia, respiratory collapse and death. Warnings & precautions: The following risks are higher in the case of intravascular administration of iodinated contrast media but are also relevant for enteral use. Gastrografin can be associated with anaphylactoid/hypersensitivity or other idiosyncratic reactions, characterised by cardiovascular, respiratory or cutaneous manifestations, and ranging to severe reactions including shock. Delayed reactions may occur (hours later or up to several days). Medication for the treatment of hypersensitivity reactions as well as readiness for institution of emergency measures are necessary. The risk of anaphylactoid/ hypersensitivity reactions is higher in the case of: history of allergic disorders or bronchial asthma; previous anaphylactoid/hypersensitivity reaction to iodinated contrast media. Patients with cardiovascular disorders are more susceptible to serious or fatal outcomes of severe anaphylactoid/hypersensitivity reactions. Refer to prescribing information for barium sulphate when used in combination with Gastrografin. In case of prolonged retention of Gastrografin in the gastrointestinal tract (e.g. obstruction, stasis), tissue damage, bleeding, bowel necrosis and intestinal perforation may occur. Adequate hydration and electrolyte balance should be established and maintained. Because of the additives (flavourings and a wetting agent), Gastrografin must not be used intravascularly. Gastrografin contains sodium Interactions: Hypersensitivity reactions can be aggravated in patients on beta-blockers. Previous treatment (up to several weeks) with Interleukin-2 is associated with an increased risk of delayed reactions to Gastrografin. Diagnosis and treatment of thyroid disorders with thyrotropic radioisotopes may be impeded for up to several weeks after administration of iodinated contrast agents. **Pregnancy & lactation:** No data on use in pregnant women. Animal studies do not indicate harmful effects on embryonal/foetal development. Caution should be exercised when using in pregnant women. It is unknown whether the active ingredients are excreted in human breast milk. Intravascular use has shown that salts of the diatrizoic acid are excreted in breast milk. A decision on the use of Gastrografin / discontinuation of breast-feeding should be made taking into account the benefit of breast-feeding to the child and the benefit of administering Gastrografin to the woman. **Undesirable effects:** Usually mild to moderate and transient in nature, however severe and life threatening reactions as well as deaths have been reported. Vomiting, nausea and diarrhoea are the most frequently recorded reactions. Other recorded reactions are: anaphylactoid shock; anaphylactoid / hypersensitivity reaction; systemic hypersensitivity is mostly mild and occurs generally in the form of skin reactions, however severe hypersensitivity reaction cannot be excluded; hyperthyroidism; fluid and electrolyte imbalance; disturbances in consciousness; headache; dizziness; cardiac arrest; tachycardia; shock; hypotension; bronchospasm; dyspnoea; medication aspiration; pulmonary oedema following aspiration; aspiration pneumonia; existing enteritis or colitis may be temporarily exacerbated; in case of obstruction, prolonged contact with bowel mucosa can lead to erosions and bowel necrosis; intestinal perforation; abdominal pain; oral mucosal blistering; toxic epidermal necrolysis; urticaria, rash; pruritus; erythema; oedema face; pyrexia; sweating. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** Disorders of water and electrolyte balance caused by overdose should be corrected. **Incompatibilities:** This medicinal product must not be mixed with other medicinal products except those mentioned in Posology & method of administration (SmPC Section 4.2). **Special Precautions for Storage:** Protect from light and X-rays. Store below 25 °C. Contrast medium solution not used within 72 hours after opening the bottle must be discarded. **Legal Category:** P. **Package Quantities & Basic NHS Costs:** 10 x 100ml bottles £175.00 **MA Number(s):** PL 00010/0537. **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** November 2018

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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