Gastrografin® (sodium amidotrizoate and meglumine amidotrizoate)

Gastrografin® (sodium amidotrizoate and meglumine amidotrizoate) gastroenteral solution

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

Presentation: 100 ml bottle of aqueous solution for enteral use; 1 ml solution contains: 100 mg sodium amidotrizoate (sodium diatrizoate) and 660 mg 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 500 ml Gastrografin dilution (diluted with 4-5 times its volume of water); ***Children up to 5 years of age:*** up to 500 ml 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 100 ml 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. It is recommended to monitor thyroid function in neonates, especially preterm infants, who have been exposed to Gastrografin, either through the mother during pregnancy or in the neonatal period, as exposure to excess iodine may cause hypothyroidism, possibly requiring treatment. Refer to prescribing information for barium sulphate preparation 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 (SmPC Section 4.4). **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, hypothyroidism (reported mostly in neonates, especially preterm neonates); 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 ºC. 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 100 ml 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:** April 2020.

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com