Package leaflet: Information for the user 3223
15.03.24[5]

Gastrografin® Gastroenteral Solution

Sodium amidotrizoate and meglumine amidotrizoate

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor giving you Gastrografin (the radiologist) or the X-ray department staff.
- If you get any side effects, talk to your doctor or the X-ray department staff/radiologist. This includes any possible side effects not listed in this leaflet. See section 4.

This medicine is available using the above name but will be referred to as Gastrografin throughout this leaflet.

What is in this leaflet

1. What Gastrografin is and what it is used for

Gastrografin is a contrast medium (a dye) which contains iodine. It is used to clearly show on X-rays the area of your body that your doctor wants to investigate. This will be your gullet (oesophagus), stomach or intestines (gastrointestinal tract). It may also be used to treat an intestinal obstruction in newborn babies (meconium ileus).

X-rays, like radio waves, can pass through objects and can be focused to make a picture. When you have an X-ray, the beam of rays goes through your body where it is absorbed to differing degrees by different tissues such as bones, muscles and organs. When the rays come out on the other side they make a pattern of light and shade on a film. Gastrografin helps to make this pattern clearer. The film is then examined by a specialist who will make a diagnosis.

This medicine is for diagnostic use only.

2. What you need to know before you are given Gastrografin

Do not use Gastrografin
- if you are allergic to sodium amidotrizoate, meglumine amidotrizoate, iodine or iodine-containing contrast media or any of the other ingredients of this medicine (listed in section 6)
- if you have a condition caused by too much thyroid hormone (manifest hyperthyroidism).

Warnings and precautions
Talk to your doctor or the X-ray department staff/radiologist before receiving Gastrografin

- You must tell the X-ray department staff if you have any of the following:
  - any type of **thyroid disease** (e.g. hyperthyroidism). Your thyroid function may be tested before receiving Gastrografin and you may be given thyreostatic medication (medication to reduce thyroid gland function).
  - a history of allergy or a tendency to develop hypersensitivity reactions (for example if you have hay fever, **asthma** or eczema)
  - heart or **blood circulation problems**, because in the rare event that you have an allergic reaction, it is more likely to be serious or fatal.

Gastrografin may affect the way the thyroid gland works for several weeks after being given it. If you are going to have an **iodine test for thyroid disease**, tell your doctor or the laboratory staff if you have received Gastrografin recently.

The doctor will test the thyroid function of newborns who have been exposed to Gastrografin either during pregnancy or after birth, because too much iodine can cause hypothyroidism (underactive thyroid gland), possibly requiring treatment.

Other medicines and Gastrografin
Tell your doctor or the X-ray department staff/radiologist if you are taking, have recently taken or might take any other medicines. This is particularly important for:
- beta-blockers (drugs used to treat heart or blood pressure), because they can make allergic reactions worse
- if you have been treated with a drug called interleukin, because there is a higher chance of getting delayed reactions (e.g. fever flu-like symptoms, joint pain and pruritus (itching)).

Ask the X-ray department staff if you are not sure.

Gastrografin with food and drink
Before the examination the X-ray department staff should make sure that you have had enough to drink and that any imbalances in your body water and body salts are corrected.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the doctor or X-ray department staff /radiologist for advice before receiving this medicine.

Gastrografin contains sodium
Gastrografin with anise oil for oral use
This medicine contains from 225.60 to 376.00 mg of sodium (main component of cooking salt) in each dose (60-100 ml). This is equivalent to 11.28-18.8% of the recommended maximum daily dietary intake of sodium for an adult.

Gastrografin with anise oil for rectal use
This medicine contains from 470.00 to 626.67 mg of sodium (main component of cooking salt) per adults dosage. This is equivalent to 23.50-31.33% of the recommended maximum daily dietary intake of sodium for an adult.

Gastrografin with anise oil in combination with barium sulfate
This medicine contains 112.80 mg of sodium (main component of cooking salt) in each dose (30 ml). This is equivalent to 5.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How you will be given Gastrografin

The X-ray department staff will explain how everything works and what position you should lie in on the X-ray table.

The dose of Gastrografin and how it will be given will depend on the type of investigation. The dose range is usually from 2 ml to 125 ml Gastrografin. This may be diluted depending on the type of investigation.

Gastrografin is either drunk as a solution or given as an enema, a liquid that is forced by low pressure into the anus. It must not be given by injection into the blood vessels.

If you receive more Gastrografin than you should
Overdosing is unlikely. If it does happen the radiologist will treat any symptoms that follow.

If you have any further questions on the use of this medicine, ask your doctor or the X-ray department staff/radiologist for advice before receiving this medicine.

Please tear/detach here

The following information is intended for healthcare professionals only:
Information for Healthcare Professionals

Gastrografin® Gastroenteral Solution

Sodium amidotrizoate and meglumine amidotrizoate

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gastrografin gastroenteral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains: 100 mg sodium amidotrizoate (sodium diatrizoate) and 660 mg meglumine amidotrizoate (meglumine diatrizoate).

Excipients with known effect:
Gastrografin contains sodium, see section 4.4.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gastroenteral solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use by oral or rectal administration only.
Gastrografin is a contrast medium for the radiological examination 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.

4.2 Posology and method of administration

Dosage for oral use
The dosage is dependent on the type of examination and the age of the patient.

Adults and 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 (CT)
0.5 - 1.5 litres of approximately 3% Gastrografin solution
(30 ml Gastrografin/1 litre of water).
Older and cachectic patients: Dilution with an equal volume of water is recommended.
Children
Children (up to 10 years of age): 15-30 ml (can be diluted with twice its volume of water)
Infants and young children: 15-30 ml (diluted with 3 times its volume of water)

Dosage for rectal use (including therapy of uncomplicated meconium ileus)

Adults
Up to 500 ml Gastrografin dilution (diluted with 3 - 4 times its volume of water)
Children
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. Advantage is taken of the high osmotic pressure of the contrast medium: the surrounding tissue is forced to release considerable amounts of fluid, which then flows into the gut and dissolves the inspissated meconium.

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. Owing to its high osmolarity, Gastrografin may cause the loss of a large amount of fluid into the intestines. An intravenous drip must therefore be set up before the enema is given and fluid should be 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.

Dosage for Gastrografin in combination with barium sulphate:
Oral and rectal administration.

Adults
In adult patients, addition of approximately 30 ml Gastrografin to the usual dose of barium should be adequate.
Children
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.

If necessary (in cases of pylorospasm or pyloric stenosis), the portion of Gastrografin in the suspension may be further increased. 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.

4.3 Contraindications

Hypersensitivity to iodine-containing contrast media. Manifest hyperthyroidism.

Gastrografin must not be administered undiluted in patients with low plasma volume, as for example in newborns, infants, children and in dehydrated patients, since hypovolaemic complications can be particularly serious in these 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.

4.4. Special warnings and precautions for use

The following risks are higher in the case of intravascular administration of iodinated contrast media but are also relevant for the enteral use of Gastrografin.

Hypersensitivity
As with other contrast agents, Gastrografin can be associated with anaphylactoid/hypersensitivity or other idiosyncratic reactions, characterized by cardiovascular, respiratory or cutaneous manifestations, and ranging to severe reactions including shock.

Delayed reactions may occur (hours later or up to several days) (see section 4.8).

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 case of:
- any history of allergic disorders,
- history of bronchial asthma,
- a previous anaphylactoid/hypersensitivity reaction to iodinated contrast media.

Patients with cardiovascular disorders are more susceptible to serious or even fatal outcomes of severe anaphylactoid/ hypersensitivity reactions.

Thyroid dysfunction
In neonates, especially preterm infants, who have been exposed to Gastrografin, 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.

Barium sulphate
If Gastrografin is used together with barium sulfate preparations, attention must be drawn to the contraindications, warnings and possible side effects relevant to the preparation.

Gastrografin contains sodium
Gastrografin with anise oil for oral use
This medicinal product contains from 225.60 to 376.00 mg of sodium in each dose (60-100 ml), equivalent to 11.28-18.8% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Gastrografin with anise oil in combination with barium sulfate
This medicinal product contains 112.80 mg of sodium in each dose (30 ml), equivalent to 5.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Gastrografin with anise oil for rectal use
This medicinal product contains 470.00-626.67 mg sodium per adults dosage equivalent to 23.5-31.33% of the maximum daily intake of sodium with food of 2 g recommended by the WHO for adults.

Gastrointestinal
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.

Hydration
Adequate hydration and electrolyte balance should be established and maintained in the patients, since the hyperosmolarity of Gastrografin may cause dehydration and electrolyte imbalance.

Because of the additives (flavourings and a wetting agent), Gastrografin must not be used intravascularly.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice:
- itching of the skin, rash, wheals on the skin (urticaria)
- difficulty breathing, gagging, feeling of suffocation
- swelling of the face, neck or body
- itchy or watery eyes, tickling in the throat or nose, hoarseness, coughing or sneezing
- headache, dizziness, feeling faint
- feeling particularly hot or cold, sweating
- paleness or reddening of the skin
- chest pain, cramp, tremor
- feeling sick

Tell the radiologist or X-ray staff immediately as these may be the first signs of allergic reaction or shock. Your investigation will need to be stopped, and you may need further treatment.

Apart from the symptoms listed above the other side effects that you might experience are:
- feeling sick or being sick
- diarrhoea
- anaphylactic shock (a very severe allergic reaction)
- allergic-type skin reactions including itching, redness, wheals on the skin
- overactive thyroid gland (hyperthyroidism)
- disorder of your body water and body salts balance
- fainting, dizziness, headache
- fast heart beat, sudden stopping of the heart (cardiac arrest), low blood pressure, shock
- difficulty breathing, swelling or fluid in the lungs. If Gastrografin gets into your lungs by accident it may cause fluid to collect in your lungs
- abdominal pain, holes in the gut wall (intestinal perforation)
- blistering inside the nose or mouth
- severe skin disease (red, blistered, bleeding, painful skin, which may affect the lips, eyes, mouth, nose and genitals too)
- rash, redness of the skin
- swelling of the face
- fever, sweating
- Underactive thyroid (hypothyroidism) – this has been reported mainly in young children/newborns, especially premature newborns. Signs may include, for example, conditions such as jaundice (yellow skin or eyes), a large soft spot on the head (fontanel), constipation, large swollen tongue, floppiness (weak muscle tone), feeding difficulties and sleepiness.

If you currently have inflammation of the intestine or bowel (enteritis or colitis), this may temporarily get worse. If you currently have a blockage in your bowel, this can lead to Gastrografin staying in the bowel for longer than usual, which may damage the lining of the bowel.

Delayed reactions can occur, if you are concerned you should contact your doctor.

Reporting of side effects
If you get any side effects, talk to your doctor, radiologist or X-ray department staff.This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Gastrografin
- Keep this medicine out of the sight and reach of children.
- The product should be used within 72 hours once opened. Unused product should be discarded.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Store in the original packaging. Protect from light and X-rays.
- If your medicine becomes discoloured or shows any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
What Gastrografin contains
The active substances are sodium amidotrizoate and meglumine amidotrizoate.1 ml of solution contains 100 mg sodium amidotrizoate and 660 mg meglumine amidotrizoate. Contains iodine 370 mg/ml.
The other ingredients are disodium edetate, saccharin sodium, star anise oil, polysorbate 80 and purified water.

What Gastrografin looks like and contents of the pack
Gastrografin is a clear, colourless solution in a brown glass bottle with a pilfer proof screw cap.
Each pack of Gastrografin contains one 100 ml brown glass bottle.

Manufacturer and product licence holder
Gastrografin is manufactured by BerliMed, Poligono Industrial Santa Rosa, Sector 32, C, 28806 Alcala de Henares, Madrid, Spain. Procured from the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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4.5 Interaction with other medicinal products and other forms of interaction
Hypersensitivity reactions can be aggravated in patients on betablockers.

Interleukin-2: Previous treatment (up to several weeks) with Interleukin-2 is associated with an increased risk of delayed reactions to Gastrografin.

Interference with diagnostic tests
Radioisotopes: Diagnosis and treatment of thyroid disorders with thyrotropic radioisotopes may be impeded for up to several weeks after administration of iodinated contrast agents due to reduced radioisotope uptake.

4.6 Fertility, pregnancy and lactation
Pregnancy
Adequate and well-controlled studies in pregnant women have not been conducted.

Animal studies do not indicate direct or indirect harmful effects with respect to embryonal/foetal development (see section 5.3).

Caution should be exercised when using Gastrografin in pregnant women.

Breast-feeding
It is unknown whether sodium amidotrizoate or meglumine amidotrizoate are excreted in human breast milk. Intravascular use has shown that salts of the diatrizoic acid are excreted in breast milk. A decision on whether to continue / discontinue breast-feeding or continue / discontinue therapy with Gastrografin should be made taking into account the benefit of breast-feeding to the child and the benefit of administering Gastrografin to the woman.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
Undesirable effects in association with the use of iodinated contrast media are 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.

The following undesirable effects have been recorded in association with the use of Gastrografin. The most appropriate MedDRA term is used to describe a certain reaction and its synonyms and related conditions.

Immune system disorders, anaphylactic reaction/hypersensitivity
Anaphylactoid shock, anaphylactoid / hypersensitivity reaction. Systemic hypersensitivity is mostly mild and occurs generally in the form of skin reactions. However, the possibility of a severe hypersensitivity reaction cannot be entirely excluded (see section 4.4).

Endocrine disorders
Hyperthyroidism, hypothyroidism*
(*Reported mostly in neonates, especially preterm neonates [see section 4.4]).

Metabolism and nutrition disorders
Fluid and electrolyte imbalance

Nervous system disorders
Disturbances in consciousness, headache, dizziness

Cardiac disorders
Cardiac arrest, tachycardia

Vascular disorders
Shock, Hypotension

Respiratory, thoracic and mediastinal disorders
Bronchospasm, dyspnoea, medication aspiration, pulmonary oedema following aspiration, aspiration pneumonia

Gastrointestinal disorders:
The hypertonic Gastrografin solution may give rise to diarrhoea, but this ceases as soon as the intestine has been emptied. Existing enteritis or colitis may be temporarily exacerbated. In case of obstruction, the prolonged contact with bowel mucosa can lead to erosions and to bowel necrosis. Other undesirable effects include vomiting, nausea, diarrhoea, intestinal perforation, abdominal pain and oral mucosal blistering.

Skin and subcutaneous tissue disorders
Toxic epidermal necrolysis, urticaria, rash, pruritus, erythema, oedema face

General disorders and administration site conditions
Pyrexia, sweating

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose
Disorders of water and electrolyte balance caused by overdose should be corrected.

5. PHARMACOLOGICAL PARTICULARS
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Water-soluble, nephrotropic, high osmolar X-ray contrast media, ATC code: V08AA01
Gastrografin does not exert a pharmacological effect. It is an iodine containing contrast medium, iodine being radio-opaque.

5.2 Pharmacokinetic properties
Only 3% of amidotrizoic acid, the radio-opaque agent of Gastrografin, is absorbed following oral administration. If a perforation of the gastrointestinal tract is present, Gastrografin finds its way into the abdominal cavity or the surrounding tissue, where it is absorbed and finally excreted via the kidneys.

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of systemic toxicity, genotoxicity, toxicity to reproduction, local tolerance and contact-sensitizing potential.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
disodium edetate
saccharin sodium
star anise oil
polysorbate 80
purified water

6.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned in section 4.2.

6.3 Shelf life
Shelf life (unopened): 4 years
Shelf life (opened): 72 hours

6.4 Special precautions for storage
Store in the original packaging. Protect from light and X-rays.

6.5 Nature and contents of container
Each pack of Gastrografin contains one 100 ml brown glass bottle with a pilfer proof screw cap.

6.6 Special precautions for disposal and other handling
At temperatures below 7 ºC Gastrografin tends to crystallize, but this can be reversed by gently warming and shaking the bottle. This phenomenon has no effect on the effectiveness or stability of the preparation.

The product should be inspected visually for particles prior to administration. Only clear solution free from particles should be used.

Contrast medium solution not used within 72 hours after opening the bottle must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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