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.

4.5 Interaction with other medicinal products and other forms of interaction

Hypersensitivity reactions can be aggravated in patients on beta-blockers.

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:

Saudi Arabia:
The National Pharmacovigilance Centre (NPC)
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Other Countries:
Please contact the relevant competent authority.

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

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 sodium
hydroxide
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): 2 years
Shelf life (opened): 72 hours

6.4 Special precautions for storage

Protect from light and X-rays. Store below 30 °C.

6.5 Nature and contents of container

Packs of 1 x 100 ml brown glass bottles with pilfer proof screw caps.

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.

7. MARKETING AUTHORISATION HOLDER

Bayer AG
51368 Leverkusen,
Germany.

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Last Renewal: 05-05-2024

9. DATE OF REVISION OF THE TEXT

14 April 2023