

Name of the medicinal product

Gastrografin

Qualitative and quantitative composition in terms of the active substance(s)

100 ml gastroenteral solution contain 10 g sodium amidotrizoate and 66 g meglumine amidotrizoate (sodium diatrizoate and meglumine diatrizoate).

Pharmacodynamic properties

The contrast-giving substance of Gastrografin is a salt of the amido(dia-)trizoic acid in which the X-ray absorbing iodine is present in a stable chemical bond. The physico-chemical characteristics of Gastrografin are listed below :

Iodine concentration (mg/ml)	370
Osmolality (osm/kg H ₂ O) at 37 °C	2.15
Viscosity (mPa·s) at 20 °C at 37 °C	18.5 8.9
Density (g/ml) at 20 °C at 37 °C	1.427 1.417
pH-value	6.0-7.0

Pharmacokinetic properties

Absorption of amidotrizoic acid, the radiopaque agent of Gastrografin, following oral administration is only 3 %. Even in the absence of perforation, higher levels of absorption - demonstrated by opacification of the renal calyces and ureters - were observed in some patients.

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.

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.

Indications

This medicinal product is for 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 sulfate).
- Treatment of uncomplicated meconium ileus.
- Computerized tomography in the abdominal region

Dosage and method of administration

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

Because of its high osmotic pressure and the tendency to absorption from the intestine, Gastrografin should not be administered to newborns, infants and young children in doses higher than those recommended. In newborns and infants low osmolar contrast media can often be used more safely than the high osmolar Gastrografin.

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 and over

Visualization of the stomach: 60ml

Follow-through examination of the gastrointestinal tract: a maximum of 100ml

For elderly and cachectic patients dilution with an equal volume of water is recommended.

Children

Newborns, infants and young children: 15-30ml (diluted with 3 times its volume of water)

Children (up to 10 years of age): 15-30ml (can be diluted with twice its volume of water)

Computerized tomography (CT)

0.5 - 1.5 l of an approx. 3 % Gastrografin solution (30 ml Gastrografin/1 l water).

Dosage for rectal use (incl. therapy of uncomplicated meconium ileus)

Adults

Up to 500ml Gastrografin dilution (diluted with 3-4 times its volume of water)

Children

Children (up to 5 years of age): up to 500ml Gastrografin dilution (diluted with 5 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)

Dosage in combination with barium sulfate

Adults and children of 10 years of age and over

In addition to the usual dose of barium sulfate: 30 ml Gastrografin

Children

In addition to the usual dose of barium sulfate:

Children (up to 5 years of age): 2-5 ml Gastrografin to 100 ml barium sulfate suspension

Children (from 5 – 10 years of age): 10 ml Gastrografin to 100 ml barium sulfate suspension.

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

Contraindications

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

Gastrografin must not be administered undiluted in patients with suspected possibility of aspiration or broncho-esophageal fistula, since hyperosmolarity may cause acute pulmonary edema, chemical pneumonia, respiratory collapse and death.

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**

Particularly careful risk-benefit assessment is required in patients with known hypersensitivity to Gastrografin or any of its ingredients due to an increased risk for anaphylactoid/hypersensitivity reactions.

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 “Undesirable effects”).

Medication for the treatment of hypersensitivity reactions as well as preparedness 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

Particularly careful risk-benefit assessment is required in patients with a previous anaphylactoid/hypersensitivity reaction to any other iodinated contrast medium because of an increased risk of anaphylactoid/hypersensitivity reactions in these patients.

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

- **Thyroid dysfunction**

Particularly careful risk-benefit assessment is required in patients with known or suspected hyperthyroidism or goiter, as iodinated contrast media may interfere with thyroid function, aggravate or induce hyperthyroidism and thyrotoxic crisis.

Testing of thyroid function prior to Gastrografin administration and/or preventive thyrostatic medication may be considered in patients with known or suspected hyperthyroidism.

In neonates, specially 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 sulfate

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.

- 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.

Interaction with other medicinal products and other forms of interaction

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.

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/fetal development (see “Preclinical safety data”).

Caution should be exercised when using Gastrografin in pregnant women.

Lactation

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After intravascular use, salts of the diatrizoic acid are excreted in human breast milk. However, at recommended doses of Gastrografin no effects on the breast-fed child are anticipated. Breast-feeding is probably safe, especially in view of the low enteral absorption of Gastrografin.

Effects on ability to drive or use machines

Not known.

Undesirable effects

Frequency of adverse reactions from spontaneous reports and literature:

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 diarrhea are the most frequently recorded reactions.

The table below reports adverse reactions by MedDRA system organ classes (MedDRA SOCs).

System Organ Class	Common (≥1/100)	Rare (<1/1,000)	Not Known
Immune system disorders		Anaphylactoid shock Anaphylactoid/hypersensitivity reaction	
Endocrine disorders		Hyperthyroidism	Hypothyroidism
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 Dyspnea Medication aspiration Pulmonary edema following	

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System Organ Class	Common (≥1/100)	Rare (<1/1,000)	Not Known
		aspiration Aspiration pneumonia	
Gastrointestinal disorders	Vomiting Nausea Diarrhea	Intestinal perforation Abdominal pain Oral mucosal blistering	
Skin and subcutaneous tissue disorders		Toxic epidermal necrolysis Urticaria Rash Pruritus Erythema Edema face	
General disorders and administration site conditions		Pyrexia Sweating	

The most appropriate MedDRA term is used to describe a certain reaction and its synonyms and related conditions.

Immune system disorders, anaphylactoid reaction/hypersensitivity:

Systemic hypersensitivity is rare, mostly mild and occurs generally in the form of skin reactions. However, the possibility of a severe hypersensitivity reaction cannot be entirely excluded (see "Special warnings").

Gastrointestinal disorders:

The hypertonic Gastrografin solution may give rise to diarrhea, 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.

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 the section "Dosage".

Nature and contents of container

Screw bottles of 100 ml, amber, glass type III.

Instructions for use / handling

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Unused Gastrografin in opened containers must be discarded within 72 hours after first opening the container.

Special Precaution for Use

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

Manufacturer

Berlimed S.A., Spain.

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