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Gastrolux®

370 mg/ml solution

Aqueous solution for oral and rectal use

Therapeutic indications

- For the x-ray imaging of the gastrointestinal tract, particularly when the use of barium sulfate is undesired or contraindicated. In suspicion of partial or complete stenosis, occlusion, risk of perforation, acute bleeding, other acute conditions, status post gastric and intestinal resection (risk of perforation, suture insufficiency, megacolon).
- Early diagnosis of a perforation or anastomosis insufficiency in the oesophagus and gastrointestinal tract which is not visible with x-rays.
- Imaging of foreign bodies and tumours prior to endoscopies as well as gastrointestinal fistulas.
- Delimitation of the gastrointestinal tract in computer tomography (CT) of the abdomen and pelvis minor.
- Together with barium sulfate to accelerate gastrointestinal passage.

Qualitative and quantitative composition

1 ml (corresponding to approx. 1.42 g) Gastrolux® 370 mg/ml solution contains 660 mg amidotrizoic meglumin and 100 mg sodium amidotrizoate (corresponding to 370 mg bound iodine) in aqueous solution.

Iodine concentration	370 mg/ml
Physical properties	
Osmolality at 37 °C	2090 mOsm/kg H_2O
Viscosity at 37 °C	8.7 mPa s
Density at 37 °C	1.42 g/cm^3
pH parameter	6.0 - 7.6

Nature and contents of container

Gastrolux® 370 mg/ml solution is available in 100 ml screw top bottles made of brown glass type III with originality closure of polyethylene.

Pack sizes

1 bottle containing 30 ml, 100 ml
10 bottles, each containing 30 ml, 100 ml
20 bottles, each containing 30 ml, 100 ml

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Partial English translation of the SPC of the medicinal product approved in Germany in February 2008

Posology and method of administration

Gastrolux® 370 mg/ml solution is intended for oral use as well as rectal application. The dilutions shown in the table are recommended for safe use. Due to the high osmolarity, concentrated **Gastrolux®** 370 mg/ml solution may cause lung oedema in aspiration and in rectal use, it may cause fluid loss via the intestine.

Oral use

The dosage primarily depends on the inquiry as well as the anatomical conditions of the respective patient. The volume to be applied must be determined by the examining physician in the individual case. In older and kachectic patients, dilution with equal parts of water (1:1) is recommended.

Based on experience, the following average quantities are administered:

- for the imaging of the oesophagus and cardia, approx. 30 ml
- for the imaging of the stomach and duodenum, approx. 60 ml
- for imaging the entire gastrointestinal tract – approx. 100 ml
- for early diagnosis of a perforation or anastomosis insufficiency in the oesophagus and gastrointestinal tract, the patient drinks 100 ml **Gastrolux®** 370 mg/ml solution. If the suspected lesion cannot be clearly identified in the x-ray image, the chemical reaction can be utilised for clarification. **Gastrolux®** 370 mg/ml solution which has moved out of the gastrointestinal tract is absorbed via the peritoneum, passes into the blood circulation and is excreted via the kidneys. Within 0.5 - 2 hours after the administration of **Gastrolux®** 370 mg/ml solution, the contrast agent can be confirmed in the urine through precipitation with concentrated hydrochloric acid (5 ml urine with 5 drops of concentrated HCl) as a white precipitate with typical crystal formation.

Rectal application (after dilution)

In adults, 500 ml diluted **Gastrolux®** 370 mg/ml solution (dilution with the 2-3-fold amount of water in a ratio of 1:3 to 1:4) are generally sufficient for imaging the colon and rectum.

Dilution recommendations for oral and rectal application:

	Oral application		Rectal application	
	Dilution	Iodine content of the mixture	Dilution	Iodine content of the mixture
Adults	Gastrolux® 370 mg/ml solution undiluted	37 g/100 ml	1 part Gastrolux® 370 mg/ml solution and 2 to 3 parts water	9 – 12 g/100 ml
Kachectic and older adults	1 part Gastrolux® 370 mg/ml solution and 1 part water	18.5 g/100 ml	1 part Gastrolux® 370 mg/ml solution and 3 parts water	9 g/100 ml

Gastrolux® 370 mg/ml solution and barium sulfate

To accelerate the gastrointestinal passage, adults and youth receive 30 ml **Gastrolux®** 370 mg/ml solution.
If required (pylorospasm, pyloric stenosis), the porridge can be made more fluid without a negative effect on the contrast.

Images

The stomach images are taken in the customary manner both when using **Gastrolux®** 370 mg/ml solution alone and in the combination with barium sulfate.
The emptying times from the stomach are the same as in barium porridge. On the other hand, the filling process in the intestine is accelerated. In pure **Gastrolux®** 370 mg/ml solution, the passage is generally ended after only 2 hours, while the **Gastrolux®** 370 mg/ml solution and barium sulfate combination may take up to 3 hours or longer in individual cases. The defecation stimulus which all patients state is the best sign that the most favourable time for the colon images has come.

Computer tomography

To mark the gastrointestinal tract in abdominal and pelvic CTs, 0.5 to 1.5 litres of a 3 - 5 % **Gastrolux®** 370 mg/ml solution are recommended.

Instruction for preparation:

Required total volume of diluted **Gastrolux®** 370 mg/ml solution (litres)	Required amount of **Gastrolux®** 370 mg/ml solution (ml)	Required amount of water (ml)
0.5	15 – 25	475 – 485
1.0	30 – 50	950 – 970
1.5	45 – 75	1425 – 1455

Contraindications

- Hypersensitivity to the medically active substances or to any of the excipients.
- Manifest hyperthyroidism.
- Newborns, infants, children as well as dehydrated hypovolaemic patients.
- Oral use in patients with a risk of aspiration (in swallowing disturbances or impaired vigilance and in patients who are not fully able to cooperate).

Special warnings and precautions for use

Gastrolux® 370 mg/ml solution must not be used intravasally. Intrathecal application of **Gastrolux®** 370 mg/ml solution must be absolutely avoided, since severe neurotoxic reactions can be expected herein.

Particularly careful consideration should be exercised before using **Gastrolux®** 370 mg/ml solution in patients in poor general status, also in the presence of latent hyperthyroidism, in nodular struma, in allergic disposition and with known contrast agent intolerance. In older and kachectic patients, dilution with equal parts of water is recommended.

If amidotrizoic acids are used in patients with severe gastrointestinal inflammation or after gastrointestinal surgeries it should be taken into consideration that in such situations absorption rates may be substantially increased.

Hydration

Disturbed water and electrolyte metabolism must be balanced before and after the examination. This particularly applies to patients with multiple myeloma, diabetes mellitus with renal function impairment, polyuria, oliguria, hyperuricaemia as well as elderly patients. In order to be able to compensate clinically relevant fluid losses as needed, Ringer's lactate solution should be readied for intravenous infusion before beginning an enema.

Thyroid function disturbance

Iodine containing x-ray contrast agents influence the thyroid gland function due to their content of free iodide and may cause hyperthyroidism in correspondingly susceptible patients. In order to avoid the occurrence of this metabolic disturbance, it is necessary to record possible thyroidal risk factors. In this regard, patients with latent hyperthyroidism and patients with functional autonomy are at risk. If the administration of iodised contrast agents is planned in patients who are potentially at risk, thyroid function must be clarified prior to the examination and hyperthyroidism must be excluded.

Contrast agent hypersensitivity

As in all iodised x-ray contrast agents, hypersensitivity reactions (allergoid reactions) may also occur after the use of **Gastrolux®** 370 mg/ml solution. However, they are significantly rarer and in the greater majority of cases, of lesser severity than after intravasal administration of contrast agents.

Allergoid reactions cannot be foreseen in individual cases due to their irregular occurrence. However it is known that allergoid contrast agent reactions occur more frequently particularly in patients with allergic disposition (allergies, bronchial asthma) and in patients with known hypersensitivity reactions to contrast agents.
Therefore an allergy history should be taken at the start of every contrast agent examination.
Due to the additional risk of severe hypersensitivity reactions which require treatment, contrast agents should only be used in locations where the prerequisites for emergency treatment are provided. The patient should be monitored for at least another half hour after the end of the application since experience has shown that most severe events occur within this time.

In connection with the simultaneous use of barium sulfate, the respectively applicable contra-indications, warnings and possible side effects must be taken into account.

Severe cardiovascular disorders

In patients with severe heart disorders, particularly heart failure and coronary heart disease, there is a higher risk of severe hypersensitivity reactions.

100 ml solution contain 16.8 mmol (386 mg) sodium. This must be taken into account in persons with a sodium controlled (low salt) diet.

Interaction with other medicinal products and other forms of interaction

Patients who are taking beta blockers may experience intensified hypersensitivity symptoms. It must be noted that the preceding use of beta blockers may mean that the treatment of hypersensitivity reactions with beta agonists may be unsuccessful.
It is reported in the literature that known contrast agent reactions such as erythema, fever or flu-like symptoms may occur more frequently and especially with a delay after the administration of x-ray contrast agents in patients who were simultaneously treated with Interferons or Interleukins. A cause for this is not yet known.

Influence on laboratory tests

The absorption capacity of the thyroid tissues for radioisotopes for thyroid diagnostics can be reduced for up to 2 weeks through the administration of **Gastrolux®** 370 mg/ml solution, and longer in some cases.

Pregnancy and breast-feeding

Reproduction toxicological studies in intravenous administration of meglumin or sodium amidotrizoate showed no evidence of a teratogenic or embryotoxic potential.
In humans, however, the harmlessness of the use of **Gastrolux®** 370 mg/ml solution during pregnancy is not proven. Since radiation load should be avoided where possible during this time in any case, this is already sufficient cause for careful consideration of the benefits of any x-ray examination – whether it is done with or without a contrast agent.
In contrast agent examinations during pregnancy, the pronounced iodine sensitivity of the foetal thyroid gland should be taken into account in every case.
If an examination with **Gastrolux®** 370 mg/ml solution is required during the breast-feeding period, there is no restriction based on the information about the indication.

Effects on ability to drive and use machines

None known.

Undesirable effects

When taking or using **Gastrolux®** 370 mg/ml solution, the following side effects may occur, whose evaluation is based on the following frequency statements:

common:	occurrence	< 1 : 10
	however	≥ 1 : 100
uncommon:	occurrence	< 1 : 100
	however	≥ 1 : 1.000
rare:	occurrence	< 1 : 1.000
	however	≥ 1 : 10.000
very rare:	occurrence	< 1 : 10.000

Hypersensitivity reactions

Since – even after gastrointestinal application – approx. 3-10 % of the contrast agent may be passed into the blood circulatory system, reactions as they are also described for intravasal contrast agent administration must be expected in terms of allergoid symptoms. However, such reactions are rare, generally slight and usually occur in the form of skin reactions (urticaria, erythema, exanthema). Even initially slight and unnoticeable symptoms may develop into severe reactions and shock (see Special warnings and precautions for use).

Disturbances in the endocrine system

In manifest thyroid hyperfunction, the application of **Gastrolux®** 370 mg/ml solution may cause metabolic imbalance, ranging to a thyrotoxic crisis.

Reactions of the respiratory tract

In the case of aspiration of **Gastrolux®** 370 mg/ml solution, lung oedema may occur in very rare cases.

Gastrointestinal disturbances

In undiluted form, but also in combination with a large volume of fluids after dilution, **Gastrolux®** 370 mg/ml frequently causes diarrhoea, however this subsides after the intestine is emptied. Nausea and vomiting are frequent. Inflammatory changes of the intestinal mucous membranes may be temporarily intensified. In rectal use in the case of an obstruction, erosion, bleeding and intestinal necrosis may occur.

Reactions of the skin and subcutaneous tissues

Very rarely, urticarial skin reactions were observed.

Overdose

There is no acute risk of poisoning in the approved uses of **Gastrolux®** 370 mg/ml solution.
Overdose related fluid and electrolyte shifts can, if applicable, be corrected through targeted infusion therapy.

Pharmaceutical particulars

List of excipients

Sodium hydroxide, Saccharine sodium 2 H_2O, Polysorbate 80, Star-anise oil, Sodium edetate (Ph. Eur.), Citric acid, Water for injection purposes.

Incompatibilities

Please refer to the section "Posology and method of administration".

Shelf life

The expiry date is based on a 3 year shelf life.
Until complete use within 72 hours, the bottle must be firmly re-closed after every use.

Special precautions for storage

Protect from light and x-rays.

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