Package leaflet: Information for the patient

Gastrografin®

660mg/ml + 100 mg/ml

Oral and Rectal Solution

Meglumine amidotrizoate

Sodium amidotrizoate

Read all of this leaflet carefully before you start using 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 the 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.

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 (hypersensitive) to meglumine amidotrizoate, sodium amidotrizoate 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).

Do not use Gastrografin undiluted

- if you have a low blood volume. This can happen, for example, if you have lost water through diarrhoea or vomiting. It may also happen in newborns, infants and children. Complications due to low blood volume can become particularly serious.
- if it is possible that Gastrografin could accidentally get into your lungs. This could cause serious side effects and could even be fatal.

Warnings and Precautions

Talk to the doctor or X-ray department staff before using Gastrografin. You must tell the X-ray department staff if you suffer or have suffered from

- An over active thyroid gland (hyperthyroidism) or an enlarged thyroid gland (goiter) as iodinated contrast media may induce hyperthyroidism and thyrotoxic crisis (severe complication of an overactive thyroid).
- allergy (hypersensitivity) to iodine or iodine-containing contrast media; a previous reaction to any contrast medium; other allergies such as hay fever, hives; asthma
- if you have a disease of your heart or blood vessels
- if you are in a very poor general state of health.
- Your thyroid function may be tested before receiving Gastrografin and you may be given medication to reduce thyroid gland function (thyreostatic medication).
- 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 an underactive thyroid gland (hypothyroidism), possibly requiring treatment.

Gastrografin may affect the way the thyroid gland works for several weeks or more 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.

Other medicines and Gastrografin

Please tell the radiologist or X-ray department staff 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 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. This is particularly important for babies, children and older patients as well as people with

- a disease of the bone marrow (multiple myeloma)
- diabetes with complications

- polyuria (production of large amounts of urine which is pale in colour)
- oliguria (production of small amounts of urine)
- a disorder affecting the amount of uric acid in your blood.

Your doctor may recommend a cleansing of the bowel before Gastrografin is used.

Pregnancy and breast-feeding

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

Driving and using machines

It is unknown if taking Gastrografin will affect your ability to drive or operate machinery.

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 your age and the type of investigation. Gastrografin 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.

4. Possible side effects

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

Side effects you may get after being given a contrast medium like Gastrografin are usually mild to moderate and do not last long.

However, severe and life-threatening reactions as well as deaths have been reported. This is more likely if you

- have a history of allergies or asthma,
- have had a previous reaction to a contrast medium.

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, running nose, 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:

Common: *may affect up to 1 in 10 people*

- feeling sick and being sick, diarrhoea

Rare: *may affect up to 1 in 1,000 people*

- If you currently have inflammation of the intestine or bowel (enteritis or colitis) this may temporarily get worse. If an obstruction exists it may hinder the passage of Gastrografin and lead to tissue damage of the bowel.
- overactive thyroid gland (*hyperthyroidism*)
- fluid and salt imbalance
- cardiac arrest, fast heart beat (*tachycardia*)
- shock, low blood pressure
- entry of medication into the respiratory tract, build-up of fluid in the lungs, inflammation of the lungs.
- bowel rupture (*intestinal perforation*), stomach (*abdominal*) pain, blistering in the lining of the mouth
- severe skin reaction with intense reddening, peeling of the top layer of skin, large blisters (*toxic epidermal necrolysis*).

Frequency Not known: *frequency cannot be estimated from the available data.*

- Underactive thyroid *(hypothyroidism)*

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, pharmacist or radiologist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. 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.
Do not use this medicine after the expiry date which is stated on the bottle label and outer carton. The expiry date refers to the last day of that month.

Store in the original package to protect from light. Protect from X-rays. Solution not used within 1 day of opening must be discarded.

This medicinal product does not require any special temperature storage conditions.

At temperatures below 7ºC Gastrografin tends to crystallise but this can be reversed by gently warming and shaking the bottle. This has no effect on the effectiveness or stability of the preparation.

6. Contents of the pack and other information

What Gastrografin contains

-The active substances are meglumine amidotrizoate and sodium amidotrizoate.

-The other ingredients are

sodium hydroxide, disodium edetate, saccharin sodium, polysorbate 80, star anise oil, purified water

1ml of solution contains Amidotrizoic Acid (dihydrate) equivalent to Amidotrizoic Acid (anhydrous) 597.30 mg, 159.24 mg Meglumine and 6.29 mg Sodium Hydroxide equivalent to 100 mg of Sodium Amidotrizoate and 660 mg of Meglumine Amidotrizoate

(and containing the equivalent of 370 mg of Iodine in combined form per ml).

One 100 ml bottle contains 10 g sodium amidotrizoate and 66 g meglumine amidotrizoate (sodium diatrizoate and meglumine diatrizoate). It contains the equivalent of 37 g Iodine in combined form in each 100 ml.

This medicine contains 374 mg of sodium (main component of cooking salt) in each bottle (100 ml). This is equivalent to 18.7% of the recommended maximum daily dietary intake of sodium for an adult.

What Gastrografin looks like and contents of the pack

Gastrografin is a clear, almost colourless, yellowish, aqueous solution supplied in bottles of 100 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bayer Limited, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland

Manufacturer:

Berli Med
Poligono Industrial
Santa Rosa s/n
Alcala de Henares
Madrid
Spain

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7. Information for healthcare professionals only

PLEASE SEE SPC FOR FULL PRESCRIBING INFORMATION

The following information is intended for medical or healthcare professionals only:

Medication for the treatment of hypersensitivity reactions as well as preparedness for institution of emergency measures are necessary.

- **Thyroid dysfunction**

Testing of thyroid function prior to Gastrografin administration and/or preventive thyreostatic medication may be considered in patients with known or suspected hyperthyroidism as iodinated contrast media may interfere with thyroid function, aggravate or induce hyperthyroidism and thyreotoxic crisis.

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 sulphate**

If Gastrografin is used together with barium sulphate 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 patients, since the hyperosmolarity of Gastrografin may cause dehydration and electrolyte imbalance.

- **Interactions**

Drugs

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

Interference with diagnostic tests

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.

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-sensitising potential.

Administration

Because of the additives (flavourings 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:

Visualisation of the stomach: 60 ml

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

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

Children:

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

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

Computerised tomography (CT):

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

Dosage for rectal use

Adults:

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

Children:

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

For the therapy of meconium ileus in the newborn, small amounts of Gastrografin solution diluted 1:3 or more are administered under fluoroscopic control.

Dosage in combination with barium sulphate

Adults and children of 10 years of age and over

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

Children:

In addition to the usual dose of barium sulphate:

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

Children (from 5 -10 years of age): 10 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 *(up to 30ml Gastrografin to 100 ml barium sulphate suspension)*.

- **Instructions for use/handling**

Contrast medium solution not used within one day after opening the bottle must be discarded.

At temperatures below 7ºC Gastrografin tends to crystallise 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.