

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

What is in this leaflet:

1. What Gastrografin is and what it is used for
2. What you need to know before you are given Gastrografin
3. How you will be given Gastrografin
4. Possible side effects
5. How to store Gastrografin
6. Contents of the pack and other information

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.

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 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.

4. Possible side effects

Like all medicines, Gastrografin 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. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):**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.

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.

Protect from light and X-rays. Do not store above 30°C.

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.

The other ingredients are disodium edetate, sodium hydroxide, saccharin sodium, star anise oil, polysorbate 80, and purified water.

What Gastrografin looks like and contents of the pack

Gastrografin is available in the following package sizes:

1 X 100 ml bottle and 10 X 100 ml bottles.

Not all pack sizes may be marketed

Manufacturer:

BerliMed S.A.

Polígono Industrial Santa Rosa

c/ Francisco Alonso s/n.

28806 Alcalá de Henares

Madrid, Spain.

for

Bayer AG – Germany.

This leaflet was last approved in 04/2023.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists