

GASTROGRAFIN®

(Gas·tro·graf·in)

Sodium amidotrizoate & Amidotrizoate meglumine

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Gastrografin. It does not contain all the available information. It does not take the place of talking to your doctor or radiologist.

The doctors conducting your X-ray examination are able to weigh up all the relevant facts. You should consult them about all aspects of this medicine as it relates to you.

If you have any concerns about using this diagnostic agent, ask your doctor or radiologist.

Keep this leaflet.

You may need to read it again.

WHAT GASTROGRAFIN IS USED FOR

Gastrografin is an X-ray contrast medium that acts like an X-ray dye when X-rays of the gastrointestinal tract are being taken. It is provided as a solution for drinking or diluted for use as an enema. Gastrografin has a sweet taste. All X-ray contrast mediums, including Gastrografin, contain iodine. X-rays are able to pass through bones in your body and thus produce a 'picture', but X-rays are unable to pass through the iodine in contrast agents.

Gastrografin enables the radiologist to see the gastrointestinal tract more clearly.

Gastrografin is often used when a barium enema or meal cannot be

used. It is sometimes added to barium to improve the X-ray picture.

Gastrografin is sometimes used to treat meconium ileus, a specific type of bowel blockage.

Gastrografin may also be used for CT scan (Computerised Tomography) in the abdominal region.

Gastrografin is only available in X-ray departments and X-ray practices for use in conjunction with taking X-rays.

The radiologist will advise the use of Gastrografin if he/she feels that it is likely to assist the X-ray examination in finding out more about your medical condition.

Ask your doctor if you have any questions about why Gastrografin is being used.

Your doctor may be using it for another reason.

BEFORE YOU ARE GIVEN GASTROGRAFIN

When you must not use it

You must not be given Gastrografin if you have an allergy to:

- Amidotrizoate meglumine and/or sodium amidotrizoate the active ingredients in Gastrografin
- iodine containing contrast agent
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not be given Gastrografin if:

- you have an overactive thyroid gland which is not being adequately treated.

Gastrografin must not be used:

- undiluted in newborns, infants, children or dehydrated patients
- in patients where there may be a possibility of inhalation of contrast media.

If you are not sure whether you should be given Gastrografin, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions especially the following:

- any allergies (e.g. seafood allergy, hay fever, hives)
- bronchial asthma
- severe heart or blood vessel disease
- known or suspected overactive thyroid gland. You may require thyroid function testing before administration of Gastrografin
- swelling of the neck caused by enlargement of the thyroid gland
- very poor general health

- dehydration, where your body does not have as much water and fluids as it should; you might feel thirsty, have a dry mouth or your urine might be darker than usual.

Tell your doctor if you are pregnant, or think you may be pregnant, or if you are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Gastrografin.

Taking other medicines

Tell your doctor if you are taking any medicines, including any that you get without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines and Gastrografin may interfere with each other.

These include:

- interleukin (used to treat some forms of cancer)
- beta blockers (medicines used to treat high blood pressure or other heart conditions)

This medicine may be affected by Gastrografin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Your doctor has more information on medicines to be careful with or to avoid while receiving Gastrografin.

HOW GASTROGRAFIN IS GIVEN

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions given, ask your doctor.

How much is given

The actual dose of Gastrografin that is right for you will be worked out by the doctor and will depend on your age and the type of X-ray examination that is being done.

How it is given

You will receive Gastrografin for drinking or diluted as an enema.

You may also receive Gastrografin for drinking along with barium sulfate, which is another type of contrast.

A cleansing of the bowels before the use of Gastrografin is recommended. Your doctor will advise you on this.

Gastrografin must not be given as an injection.

If you take too much (overdose)

As Gastrografin is administered by a doctor, overdosage is unlikely. If it does happen the doctor will treat any symptoms that follow.

Immediately tell your doctor or other medical staff or telephone the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have taken too much Gastrografin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

AFTER HAVING GASTROGRAFIN

Things you must do

Follow carefully the directions given to you by your doctor and other medical staff.

If you are going to have a test on your thyroid, tell your doctor and the medical staff that you have received Gastrografin. Gastrografin can affect thyroid tests for about 2-6 weeks after receiving it.

Things to be careful of

Delayed reactions may occur. In this case Gastrografin could prevent you from driving safely and the ability to operate tools or machines may be impaired.

SIDE EFFECTS

Tell your doctor or radiologist as soon as possible if you do not feel well whilst receiving or after being given Gastrografin.

All contrast agents can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or radiologist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea
- nausea
- vomiting.

The above list includes the more common side effects of Gastrografin. They are usually mild and short-lived. If they persist or get worse, tell your doctor.

Allergic and allergy like reactions have been observed after use of X-ray contrast agents such as Gastrografin.

Tell the doctor immediately if you notice any of the following:

- swelling of the face, eyelids, lips, tongue or other parts of the body

- watering, sore, inflamed or infected eyes, sneezing, runny nose, coughing or throat irritation
- itching or hives, redness of the skin
- difficulty breathing, gasping
- gagging, feeling of suffocation
- changes of consciousness
- flu-like symptoms, joint pain
- headache
- dizziness
- fast heartbeat
- low blood pressure
- stomach pain
- blisters in the mouth
- fever
- sweating.

This list includes side effects that can be mild and temporary or may be more serious.

Some of these side effects could be the first signs of an allergic reaction. You may need urgent medical attention or hospitalisation.

Allergic reactions occur more frequently in patients with an allergic disposition.

Severe reactions requiring emergency treatment can occur, causing low blood pressure, increase in heart rate, difficulty breathing, and swelling of the face, lips or tongue leading to severe breathing difficulties and shock may occur.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Rarely, delayed reactions can occur.

STORING GASTROGRAFIN

Storage

The X-ray department or X-ray practice will store Gastrografin under conditions advised by the

manufacturer. Shelf life and storage conditions are printed on the bottle.

Disposal

Unused Gastrografin must be discarded within 72 hours after opening the bottle.

PRODUCT DESCRIPTION

What it looks like

Gastrografin is a clear colourless liquid supplied in bottles of 100 mL and 250 mL.

Not all pack sizes may be marketed.

Ingredients

Active ingredients:

- Gastrografin – contains 100 mg sodium amidotrizoate and 660 mg amidotrizoate meglumine per mL

Inactive ingredients:

- disodium edetate
- saccharin sodium
- polysorbate 80
- star anise oil
- purified water.

Supplier

Bayer Australia Limited
 ABN 22 000 138 714
 875 Pacific Highway
 Pymble NSW 2073

Bayer New Zealand Limited
 3 Argus Place, Hillcrest,
 North Shore
 Auckland 0627

Australian registration number

Gastrografin - AUST R 10684

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See TGA website
 (www.ebs.tga.gov.au) for latest

Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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