

GASTROGRAFIN®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given GASTROGRAFIN?

GASTROGRAFIN contains the active ingredients sodium amidotrizoate and amidotrizoate meglumine. GASTROGRAFIN is a contrast agent used during an X-ray examination.

For more information, see Section [1. Why am I given GASTROGRAFIN?](#) in the full CMI.

2. What should I know before I am given GASTROGRAFIN?

Do not use if you have ever had an allergic reaction to GASTROGRAFIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor, radiographer or nurse if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

The X-ray picture is improved if your bowels are emptied. A cleansing of the bowels before you are given GASTROGRAFIN is recommended. Your doctor, radiographer or nurse will advise you on this. It is important that you still drink fluids as normal.

For more information, see Section [2. What should I know before I am given GASTROGRAFIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GASTROGRAFIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given GASTROGRAFIN?

GASTROGRAFIN is given different ways depending on your examination. It will be given by either drinking the solution or as an enema by your doctor, radiographer or nurse.

More instructions can be found in Section [4. How am I given GASTROGRAFIN?](#) in the full CMI.

5. What should I know while receiving GASTROGRAFIN?

Things you should do	Tell your doctor, radiographer or nurse if you: <ul style="list-style-type: none">• experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock• experience any asthma symptoms e.g. chest tightening.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how GASTROGRAFIN affects you.
Laboratory tests	GASTROGRAFIN can affect the results of some thyroid tests up to several weeks after receiving it.
Looking after your medicine	The X-Ray unit will store GASTROGRAFIN as required by the manufacturer.

For more information, see Section [5. What should I know while receiving GASTROGRAFIN?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

Serious side effects can include severe allergic reactions, difficulty breathing and heart attack. Common side effects can include vomiting, nausea and diarrhoea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

GASTROGRAFIN[®] (Gas-tro-graf-in)

Active ingredient: *sodium amidotrizoate and amidotrizoate meglumine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using GASTROGRAFIN. **You should also speak to your doctor, radiographer, nurse or pharmacist if you would like further information or if you have any concerns or questions about using GASTROGRAFIN.**

Where to find information in this leaflet:

- [1. Why am I given GASTROGRAFIN?](#)
- [2. What should I know before I am given GASTROGRAFIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given GASTROGRAFIN?](#)
- [5. What should I know while receiving GASTROGRAFIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given GASTROGRAFIN?

GASTROGRAFIN contains the active ingredients sodium amidotrizoate and amidotrizoate meglumine.

GASTROGRAFIN is a contrast medium (a dye) which contains iodine. It can be given orally (by mouth) by drinking the solution or given as an enema in the rectum. It is used to clearly show on X-rays or CT (computed tomography) scan areas of your gastrointestinal tract.

2. What should I know before I am given GASTROGRAFIN?

Warnings

Do not use GASTROGRAFIN if:

- you are allergic to sodium amidotrizoate and/or amidotrizoate meglumine, or any of the ingredients listed at the end of this leaflet
- have an overactive thyroid which isn't being treated
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor, radiographer or nurse if you have:

- any allergies to other iodine-containing contrast or any other allergies (e.g. shellfish, hay fever, hives, anaphylaxis) or asthma
- overactive thyroid gland or goitre (swelling in the neck)

- heart or cardiovascular disease, including heart failure or coronary artery disease
- a very poor state of general health
- are dehydrated and your body needs more fluids
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

You may be asked to stay in the X-ray department for a period of time after your examination so that the medical staff can monitor you for side effects.

Pregnancy and breastfeeding

Advise your doctor, radiographer or nurse if you are pregnant or intend to become pregnant.

Talk to your doctor, radiographer or nurse if you are breastfeeding or intend to breastfeed.

Use in children

GASTROGRAFIN is approved for use in adults, adolescents and children including full-term newborns.

Food and drink before your procedure

The X-ray picture is improved if your bowels are emptied. A cleansing of the bowels before you are given GASTROGRAFIN is recommended. Your doctor, radiographer or nurse will advise you on this.

It is important that you still drink fluids as normal. You will be advised to take fluids before and after the examination to help protect your kidneys.

3. What if I am taking other medicines?

Tell your doctor, radiographer, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

- are taking beta-blockers used for high blood pressure or heart conditions
- are taking interleukin used to treat some cancers.

Some medicines may interfere with GASTROGRAFIN and affect how it works.

If you experience an allergy-like reaction to GASTROGRAFIN, any treatment given to you may be affected by these medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GASTROGRAFIN.

4. How am I given GASTROGRAFIN?

How much to be given

The dosage of GASTROGRAFIN is based on the type of examination and your age. It may also be given diluted or mixed with another contrast called barium sulfate. The doctor, radiographer or nurse will calculate the right dose for you.

When GASTROGRAFIN is given

- GASTROGRAFIN will be given before your examination.

How GASTROGRAFIN is given

GASTROGRAFIN is given different ways depending on the examination:

1. Given orally by drinking the solution
2. Given rectally as an enema by your doctor, radiographer or nurse.

GASTROGRAFIN has a sweet taste.

If you are given too much GASTROGRAFIN

If you think that you have been given too much GASTROGRAFIN, ask the doctor, radiographer or nurse. As GASTROGRAFIN is given by the doctor, radiographer or nurse, overdose is unlikely. If it does happen, a doctor will treat any symptoms that follow.

You should immediately:

- phone the Poisons Information Centre (**by calling Australia: 13 11 26 or New Zealand 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while receiving GASTROGRAFIN?

Things you should do

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

Call your doctor, radiographer or nurse straight away if you:

- experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock
- experience any asthma symptoms e.g. chest tightening.

Remind any doctor, dentist or pharmacist you visit that you have been given GASTROGRAFIN.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GASTROGRAFIN affects you.

It is not known if GASTROGRAFIN may cause delayed reactions that could impair the ability to drive and use machines.

Laboratory tests

- GASTROGRAFIN can affect the results of some thyroid tests up to several weeks after receiving it
- Remind your doctor or medical staff after you have received GASTROGRAFIN.

Looking after your medicine

- The X-ray unit will store GASTROGRAFIN under the conditions advised by the manufacturer.
- Shelf life and storage conditions are printed on the bottle.
- Unused GASTROGRAFIN must be discarded within 72 hours after opening the bottle.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

A high level of excitement, anxiety and pain may increase the risk of side effects or make contrast agent related reactions more intense.

Allergic reaction

Some people may experience symptoms of an allergic reaction such as loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock.

Allergic reactions occur more frequently in people with a history of allergies to other contrast agents, to foods (e.g. seafood) or those who suffer from anaphylaxis, hay fever or bronchial asthma.

Most of these reactions occur within several hours of receiving GASTROGRAFIN. Rarely, some of these reactions may be delayed (up to several days after receiving GASTROGRAFIN).

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders <ul style="list-style-type: none">• Nausea• Vomiting	Speak to your doctor if you

<ul style="list-style-type: none"> • Diarrhoea • Stomach pain <p>Nervous system disorders</p> <ul style="list-style-type: none"> • Headache • Dizziness <p>General disorders</p> <ul style="list-style-type: none"> • Feeling hot • Sweating • Fever • Flushing • Skin redness 	<p>have any of these less serious side effects and they worry you.</p>
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Serious side effects

Serious side effects	What to do
<p>Immune system disorders</p> <ul style="list-style-type: none"> • Experience swelling of the face, eyelids, lips, tongue or other parts of the body • Coughing or throat irritation • Sneezing, running nose • Itching or hives • Conjunctivitis • Wheezing, shortness of breath, difficulty breathing, gasping • Gagging, feeling of suffocation • Low blood pressure • Shock <p>Nervous system disorders</p> <ul style="list-style-type: none"> • Loss of consciousness <p>Cardiac disorders</p> <ul style="list-style-type: none"> • Abnormal heartbeat (maybe faster) • Heart attack <p>Respiratory disorders</p> <ul style="list-style-type: none"> • Difficulty breathing • Change in breathing rate • Fluid on the lungs <p>Gastrointestinal disorders</p> <ul style="list-style-type: none"> • Severe stomach pain • Blistering of the mouth <p>Skin disorders</p> <ul style="list-style-type: none"> • Painful blistering or peeling of skin <p>General disorders</p> <ul style="list-style-type: none"> • Rash • Severe dehydration • Flu-like symptoms, joint pain 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor, radiographer, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration in Australia online at www.tga.gov.au/reporting-problems or in New Zealand

<https://nzphvc.otago.ac.nz/reporting/> . By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available in an X-ray unit.

What GASTROGRAFIN contains

Active ingredient (main ingredient)	Sodium amidotrizoate and Amidotrizoate meglumine (contains iodine)
Other ingredients (inactive ingredients)	Disodium edetate Saccharin sodium Polysorbate 80 Star anise oil Purified water

Do not take this medicine if you are allergic to any of these ingredients.

What GASTROGRAFIN looks like

GASTROGRAFIN is a clear, faintly yellow solution for oral administration and is supplied in amber glass bottles of 100 or 250 mL.

100 mL or 250 mL glass bottles – AUST R 10684

Not all presentations may be marketed in Australia or New Zealand.

Who distributes GASTROGRAFIN

Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073
www.bayer.com.au

Bayer New Zealand Limited
PO Box 2825
Shortland Street
Auckland 1140
Free phone 0800 229 376

This leaflet was prepared in December 2020.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information or on the Medsafe website (www.medsafe.govt.nz) for New Zealand.



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