

UROGRAFIN®

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 UROGRAFIN?

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

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

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

Do not use if you have ever had an allergic reaction to UROGRAFIN 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.

If you are to have an X-ray of your abdominal area or kidneys, you may be asked to change your diet for 2 days prior and to not eat (fast) after 6pm the evening before your procedure. It is important that you still drink fluids as normal.

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

3. What if I am taking other medicines?

Some medicines may interfere with UROGRAFIN 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 UROGRAFIN?

UROGRAFIN is injected by the doctor or radiographer into different parts of your body depending on the area of your body to be examined.

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

5. What should I know while receiving UROGRAFIN?

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 shockexperience any asthma symptoms e.g. chest tightening.
Driving or using machines	UROGRAFIN may cause delayed reactions that could impair the ability to drive and use machines.
Laboratory tests	UROGRAFIN 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 UROGRAFIN as required by the manufacturer.

For more information, see Section [5. What should I know while receiving UROGRAFIN?](#) 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 nausea, vomiting, red skin (flushing), pain sensation and feeling warm.

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.

UROGRAFIN[®] (YOU-row-graf-in)

Active ingredient: *sodium amidotrizoate and amidotrizoate meglumine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using UROGRAFIN. **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 UROGRAFIN.**

Where to find information in this leaflet:

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

1. Why am I given UROGRAFIN?

UROGRAFIN contains the active ingredients sodium amidotrizoate and amidotrizoate meglumine.

UROGRAFIN is an injectable 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, for example, your kidney, bladder, blood vessels, uterus, joints, bile ducts, fistula, spleen or seminal vesicles in the pelvis. It can also be used with computer-assisted X-ray machines (CT scanners).

UROGRAFIN is also used during an angiogram in a cardiac catheterization procedure to help the doctor visualise the blood vessels in your heart and body using an X-ray machine.

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

Warnings

Do not use UROGRAFIN if:

- you are allergic to sodium amidotrizoate and/or amidotrizoate meglumine, or any of the ingredients listed at the end of this leaflet
- have severe heart conditions or circulatory conditions like heart failure
- have an overactive thyroid which isn't being treated
- are pregnant or if you have pelvic inflammatory disease
- acute pancreatitis

- 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 valve failure, coronary artery disease or pulmonary hypertension
- cerebral arteriosclerosis
- impaired kidney or liver function
- emphysema of the lungs
- a very poor state of general health
- diabetes
- disorder of the central nervous system, including previous brain bleeds, brain injury, stroke, swelling on the brain or epilepsy
- cerebral spasmodic conditions
- demyelinating disease, such as multiple sclerosis or optic neuritis
- multiple myeloma or paraproteinaemia
- pheochromocytoma
- an auto-immune disease
- myasthenia gravis
- alcoholism or drug addiction
- homocysteinuria, a genetic disorder
- 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 or have any infections of the uterus or vagina. X-ray examinations of the uterus must not be performed during pregnancy or if you have pelvic inflammatory disease.

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

Use in children

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

Food and drink before your procedure

If you are to have an X-ray of your abdominal area or kidneys, the X-ray picture is improved if your bowels are emptied. On the two days prior to your X-ray procedure avoid flatulent food such as peas, beans, lentils, salads, fruit, dark and fresh bread and all kinds of uncooked vegetables.

You may be asked to not eat after 6pm the evening before the procedure (fasting) and may also be asked to take a laxative the evening before. If it is your child undergoing the procedure, you may be given different instructions by your doctor, radiographer or nurse.

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
- are taking metformin, a medicine used to treat diabetes.

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

If you experience an allergy-like reaction to UROGRAFIN, 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 UROGRAFIN.

4. How am I given UROGRAFIN?

How much to be given

- The dosage of UROGRAFIN is based on the area of your body that will be examined. The doctor or radiographer will calculate the right dose for you.

When UROGRAFIN is given

- UROGRAFIN will be given immediately before or during your examination.

How UROGRAFIN is given

UROGRAFIN is given different ways by the doctor or radiographer depending on the area of your body to be examined:

1. by a small needle into a vein usually in your hand or arm or
2. injected via a catheter into different parts of your body directly.

If you are given too much UROGRAFIN

If you think that you have been given too much UROGRAFIN, ask the doctor, radiographer or nurse. As UROGRAFIN 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 UROGRAFIN?

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 UROGRAFIN.

Driving or using machines

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

UROGRAFIN may cause delayed reactions that could impair the ability to drive and use machines.

Laboratory tests

- UROGRAFIN 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 UROGRAFIN.

Looking after your medicine

- The X-ray unit will store UROGRAFIN under the conditions advised by the manufacturer.

- Shelf life and storage conditions are printed on the vial or 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, radiographer, nurse 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 one (1) hour of receiving UROGRAFIN. Rarely, some of these reactions may be delayed (up to several days after receiving UROGRAFIN).

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders <ul style="list-style-type: none"> • Nausea • Vomiting • Stomach pain Nervous system disorders <ul style="list-style-type: none"> • Headache • Dizziness General disorders <ul style="list-style-type: none"> • Feeling hot • Malaise (fatigue) • Sweating • Chills or feeling cold • Swollen saliva glands • Flushing • Skin redness 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
Immune system disorders <ul style="list-style-type: none"> • Experience swelling of the face, eyelids, lips, tongue or other parts of the body • Coughing or throat irritation 	<p>Call your doctor straight away, or go straight to the Emergency</p>

<ul style="list-style-type: none"> • Itching or hives • Conjunctivitis • Wheezing, shortness of breath, difficulty breathing, gasping • Gagging, feeling of suffocation • Low blood pressure Nervous system disorders <ul style="list-style-type: none"> • Vasovagal reaction (fainting) • Loss of consciousness • Seizures (fits) • Tremors • Short term loss of sensation • Altered speech or hearing • Short term blindness or vision issues • Light sensitivity Cardiac disorders <ul style="list-style-type: none"> • Irregular heartbeat • Abnormal heartbeat (maybe faster) • Heart attack Psychiatric disorders <ul style="list-style-type: none"> • Agitation • Confusion Respiratory disorders <ul style="list-style-type: none"> • Difficulty breathing • Change in breathing rate • Slow or shallow breathing Renal disorders <ul style="list-style-type: none"> • Temporary kidney failure • Dark or little urine output General disorders <ul style="list-style-type: none"> • Blue hands or feet • Injection site reaction or pain • Pain sensation • Fluid under skin at injection site • Rash • Fever • Swelling and redness along a vein or a blood clot in a vein 	<p>Department at your nearest hospital if you notice any of these serious side effects.</p>
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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 UROGRAFIN contains

Active ingredient (main ingredient)	Sodium amidotrizoate and Amidotrizoate meglumine (contains iodine)
Other ingredients (inactive ingredients)	Sodium calcium edetate Water for injections

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

What UROGRAFIN looks like

UROGRAFIN is a clear, colourless to slightly yellow solution for injection and is supplied in glass vials or glass bottles of various sizes.

UROGRAFIN 30%:

10 x 10 mL glass ampoules – AUST R 42161

1 x 250 mL glass bottle – AUST R 42163

UROGRAFIN 76%:

10 x 50 mL glass bottle – AUST R 42157

10 x 100 mL glass bottles – AUST R 48496

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

Who distributes UROGRAFIN

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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