

Package leaflet: information for the user

Urografin® 30% w/v Solution for infusion

Sodium amidotrizoate
Meglumine amidotrizoate

Read all of this leaflet carefully before you are given this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor giving you Urografin (the radiologist) or the X-ray department staff.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or the X-ray department staff/radiologist.

In this leaflet:

1. **What Urografin is and what it is used for**
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1. What Urografin is and what it is used for

Urografin is an injectable contrast medium (a dye) which contains iodine. It is used to show the urinary tract clearly on X-rays.

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. Urografin 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. Before you are given Urografin

Do not use Urografin if:

- you are, or suspect you are, allergic (hypersensitive) to iodine or iodine-containing contrast media or any of the other ingredients of Urografin (see section 6: Further Information)
- you have an overactive thyroid gland which is not being fully

treated (manifest hyperthyroidism).

- you have heart failure.

Urografin must not be given into the space around the spinal cord because severe adverse reactions are possible.

Take special care with Urografin

You must tell the X-ray department staff if you have any of the following:

- a history of kidney disease or reduced liver or kidney function
- epilepsy, a history of seizures or other brain disorders
- a disease of blood vessels in the brain (cerebral arteriosclerosis)
- diabetes mellitus requiring treatment and/or associated with diabetic complications
- poor general health
- you have or are suspected to have an overactive thyroid gland (hyperthyroidism) or an enlarged thyroid gland as iodinated contrast media may in this situation induce hyperthyroidism and thyrotoxic crisis (severe complication of an overactive thyroid).
- a disease of the bone marrow (multiple myeloma)
- over-production of special proteins (paraproteinemia)
- you drink alcohol regularly
- a condition of allergy against parts of your body (autoimmune disorder)
- a condition in which the muscles become weak and tire easily (myasthenia gravis)
- a disorder of your blood known as homocystinuria
- a history of allergy or a tendency to develop hypersensitivity reactions (for example if you have hay fever, seafood allergy, hives or asthma), especially if you have taken a medicine like Urografin (a contrast medium) before
- poor heart function (e.g. heart failure, angina)
- previously had a reaction to any contrast media.
- allergy (hypersensitivity) to iodine or iodine-containing contrast media or any of the other ingredients of Urografin (see Section 6: Further information).

If any of these apply to you or if you are an older patient, you may be at a higher risk of having an allergic reaction or becoming unconscious/fainting. Your thyroid

function may be tested before receiving Urografin 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 Urografin either during pregnancy or after birth, because too much iodine can cause an under active thyroid gland (hypothyroidism), possibly requiring treatment.

If you have a phaeochromocytoma (tumour of the adrenal gland) you may be given a medicine called an alpha-receptor blocker before the investigation to prevent your blood pressure from rising.

Urografin may affect the way the thyroid gland works for 2 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 been given Urografin recently.

Taking or using other medicines

Please tell the radiologist or X-ray department staff if you are taking or have recently taken any other medicines, including medicines obtained without prescription. This is particularly important for:

- beta-blockers (drugs used to treat heart or blood pressure), because they can make allergic reactions worse. Beta-blockers may also make it more difficult to treat an allergic reaction.
- 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)).
- If you have kidney disease due to diabetes (diabetic nephropathy) and are taking a type of medicine called biguanides (metformin). You should inform your doctor who will probably stop the biguanides 48 hours before the examination.

Ask the X-ray department staff if you are not sure.

Using with food and drink

You may be asked to avoid foods that cause flatulence (wind) for two days beforehand. These foods include:

- peas, beans, lentils, salads, fruit
- brown or granary bread
- all kinds of uncooked vegetables.

You will be told not to eat after 6pm on the day before the examination, but you can still drink. You may be told to take a laxative the evening before the examination. Babies and

young children, however, must not fast or take a laxative. If you have a disorder of your body water and body salts balance this will be corrected before the examination.

Do not reduce the amount you normally drink before the investigation, especially if you have any of the following:

- multiple myeloma (disease of the bone marrow)
- diabetes mellitus
- polyuria (production of large amounts of urine which is pale in colour)
- oliguria (production of small amounts of urine)
- gout
- a disorder affecting the amount of calcium in your blood.

Also, fluid intake must not be reduced in babies, young children, older patients or in someone who is in a very poor general state of health where their body tissues are wasting away.

Pregnancy and breast-feeding

Tell the X-ray department staff if you are pregnant, think you may be pregnant, or are breast feeding.

Driving and using machines

You should not drive or operate machinery after the examination as you may have a delayed reaction to Urografin.

Important information about some of the ingredients of Urografin

This medicine contains 362.50 mg of sodium (main component of cooking salt) in each dose (250 ml). This is equivalent to 18.1% of the recommended daily dietary intake of sodium for an adult.

3. How you will be given Urografin

The X-ray department staff will decide how much Urografin is needed for your particular investigation. They will explain how everything works and what position you should lie in on the X-ray table. Tell the X-ray department staff if you feel anxious or if you are in any pain.

The dose of Urografin varies depending on your age, weight, heart function, blood vessels and kidneys and on your general health.

Once you lie down the Urografin will be injected into a vein. The staff in the X-ray department will observe you for at least 30 minutes after the injection just in case you have any side effects.

If you receive more Urografin 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, Urografin can cause side effects, although not everybody gets them.

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

However, as with similar contrast media, severe and life-threatening reactions, as well as deaths, have been reported.

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
- agitation
- confusion
- blue lips

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 possible side effects of Urografin are:

- feeling sick or being sick
- a sensation of pain and a general feeling of warmth
- in rare cases your kidneys temporarily stop working
- reddening or other reactions at the injection site if Urografin is not injected properly.

Very rarely severe or even life-threatening side-effects may occur and in some cases have been fatal. These include:

- lowered blood pressure
- fainting (collapse)
- circulatory failure
- an irregular, rapid heart beat which may cause the heart to suddenly stop beating altogether (cardiac arrest)

- disorders of the brain circulation leading to stroke
- fits or other brain related symptoms
- a build-up of water in the air spaces of the lung
- anaphylactic shock (a very severe allergic reaction)
- unconsciousness.

Severe skin disease (pain, reddening, large blisters, peeling of layers of skin) may develop in rare cases.

If contrast medium reaches the brain, you may also have complications such as:

- coma, temporary confusion and drowsiness
- temporary weakness of the muscles
- disturbed speech, vision or hearing
- loss of memory
- convulsions.

Delayed reactions can occasionally 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Urografin

Keep out of the reach and sight of children.

Do not use Urografin after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package to protect from light.

Protect from X-rays

Urografin should not be drawn into the syringe or the infusion bottle attached to the infusion set until immediately before examination. Vials containing contrast media solutions are not intended for the withdrawal of multiple doses.

Contrast media solution not used in one examination session must be discarded.

6. Further information

What Urografin contains

The active substances are sodium amidotrizoate and meglumine amidotrizoate.

1ml Urografin contains 40mg sodium amidotrizoate and 260mg meglumine amidotrizoate (sodium diatrizoate and meglumine diatrizoate). It contains the equivalent of 146 mg Iodine in combined form in each ml.

One 250 ml bottle contains 10 g sodium amidotrizoate, 65 g meglumine amidotrizoate (sodium diatrizoate and meglumine diatrizoate). It contains the equivalent of 35.5 g Iodine in combined form in each 250 ml.

The other ingredients are sodium calcium edetate and water for injection.

What Urografin looks like and contents of the pack

Urografin is available in 250 ml bottles.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Bayer Limited
The Atrium
Blackthorn Road
Dublin 18

Manufacturer:
BerliMed S.A.
Francisco Alonso 7,
Polígono Industrial Santa Rosa,
28806 Alcalá de Henares,
Madrid,
Spain

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