

Consumer Medicine Information

Urografin®

***Contrast Imaging Agent
Solution for Infusion - amidotrizoate 30% and 76%***

What is in this leaflet

This leaflet answers some common questions about UROGRAFIN.

This leaflet does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking UROGRAFIN against the benefits they expect it will have for you. Only the doctors conducting your X-Ray examination are able to weigh up all the relevant facts and you should consult them about all aspects of this medicine as it relates to you.

UROGRAFIN is a general sales medicine. However, it should only be used under medical supervision.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What UROGRAFIN is used for

UROGRAFIN is an X-ray contrast medium or X-ray dye that is injected directly into the bloodstream while X-rays are being taken. All injectable X-ray dyes, including UROGRAFIN, contain iodine. Just as X-rays are unable to pass through bones in your body and thus produce a 'picture', X-rays are unable to pass through the iodine in contrast dyes. When UROGRAFIN is injected into your body it is used by X-ray specialist doctors (radiologists) in one of the following ways, depending on the condition that is being investigated in your particular case:

- following injection into an arm vein, UROGRAFIN travels with the bloodstream to every organ of the body. Using sensitive computer

- assisted X-ray machines known as CT or CAT scanners, the radiologist can see the X-ray dye in your brain, abdomen or other areas of the body
- following injection into an arm vein UROGRAFIN also travels in the bloodstream to your kidneys where it is excreted from the body in your urine. The radiologist can see the X-ray dye in the kidneys, urinary system and bladder.
 - X-ray dye may also be introduced directly into the bladder or other body cavities via a catheter.

Before you have UROGRAFIN

When you must not take it

You must not be given UROGRAFIN if:

- **you have heart failure or an overactive thyroid gland which are not being adequately treated.**
- **you are pregnant or have acute inflammation of the internal female sex organs.**
X-ray examinations of the womb and tubes must not be performed during pregnancy or in the presence of acute inflammation of the internal female sex organs. Tell your doctor if this applies to you.
- **you have acute inflammation of the pancreas**
X-ray examinations of the pancreas and bile ducts must not be performed in case of acute inflammation of the pancreas. Tell your doctor if you think this might apply to you.

UROGRAFIN must not be injected into the space around your spinal cord because severe adverse reactions are possible.

Before you are given UROGRAFIN

Tell your doctor if you:-

- are pregnant or intend to become pregnant.
- are breast-feeding or intend to breast-feed. You should discuss with your doctor when to discontinue and resume breast-feeding.
- suffer from allergy (e.g. seafood allergy, hay fever, hives) or bronchial asthma.
- suffer from allergy to iodine-containing contrast media, or any other ingredients listed in this leaflet.
- have severe disturbances of liver or kidney function.
- have heart and circulatory disease.
- have advanced cerebral arteriosclerosis (disease of the brain arterioles with thickening of the blood vessel walls).

- have diabetes mellitus requiring treatment (condition where the body does not produce enough insulin or the body tissues are not able to use the insulin present).
- suffer from brain conditions and seizures.
- have cerebral spasmodic conditions.
- have a circulatory problem in the brain, e.g. history of stroke.
- have latent hyperthyroidism (overactive thyroid gland).
- have very poor general condition.
- have bland nodular goitre (swelling of the neck caused by enlargement of the thyroid gland).
- have multiple myeloma (cancer of blood cells), overproduction of special proteins (paraproteinaemia), a condition of allergy against parts of your body, or a condition in which the muscles become weak and tire easily (myasthenia gravis).
- have a special kind of high blood pressure caused by a rare tumour of the adrenal gland which sits near the kidney (pheochromocytoma).
- have pulmonary emphysema (serious lung disease that makes breathing difficult).

If you have not told your doctor about any of the above, do so before you start taking UROGRAFIN.

If you suffer from any of these, your doctor will decide whether the intended examination is possible or not.

Taking other medicines

When being treated with UROGRAFIN, you must seek your doctor's advice before taking any other medication, whether provided on a prescription or bought from a pharmacy, supermarket or health food shop including any over-the-counter medicines, vitamins or herbal medicines.

Some medication may be affected by UROGRAFIN or vice versa. Advise your doctor if you:-

- take biguanides, one type of medicine used to treat diabetes
- take special medicines daily or drink alcohol regularly
- take beta blockers, medicines used to treat high blood pressure or other heart conditions
- take interleukin

You may need to use different amounts of your medicine or a different medicine. Your doctor will be able to advise you. Your doctor and pharmacist will have a complete list of medicines to be careful of and to avoid while taking UROGRAFIN.

How to take UROGRAFIN

Before UROGRAFIN is given to you

You will be required to fast (not eat) before the examination, but you may drink as usual. Further directions on this will be given by your doctor or nurse. Do not restrict your fluid intake.

In the case of abdominal and kidney X-rays, the X-ray picture is improved if the bowels are emptied of faecal matter and gas. On the two days prior to the examination you should therefore avoid flatulent food, in particular peas, beans and lentils, salads, fruit, dark and fresh bread and all kinds of uncooked vegetables. On the day before the examination, you should refrain from eating after 6 p.m. Moreover, it can be appropriate to take a laxative (a medicine to assist bowel motion) in the evening - your doctor will advise you if necessary.

Inform your doctor if you are a diabetic because among other things he needs to check your medication especially if you are suffering from diabetic kidney disease.

If you are at all concerned, you should feel free to discuss the necessity of using UROGRAFIN with the radiologist.

How to use UROGRAFIN properly

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

UROGRAFIN will be injected by the radiologist, assisted by nursing or other X-ray staff. The radiologist will advise the use of UROGRAFIN if he/she feels that it is likely to assist the X-ray examination in finding out more about your medical condition.

The actual dose of UROGRAFIN that is right for you will be worked out by the radiologist and will depend on your general health, weight and the type of X-ray that is being done. The speed at which UROGRAFIN is injected, and the length of time until the X-rays are taken will also depend on the type of X-ray being done.

If you are given too much (overdose)

As UROGRAFIN is administered by a doctor, overdosage is unlikely. If it does happen, the doctor will treat symptoms that may occur.

Side effects

All medicines have side effects. Sometimes they are serious, most of the time they are not.

Allergy-like reactions have been observed after use of X-ray contrast media such as UROGRAFIN. Mild swelling of the face, lips, tongue, or throat, conjunctivitis, coughing, itching, running nose, sneezing and hives may be the first signs of a severe reaction.

Tell the doctor immediately if you experience any of these.

The effects outlined below are not a complete list of all possible side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them. You will be observed for about 30 minutes after your examination to ensure that you do not suffer a severe reaction to UROGRAFIN.

Side effects in association with the intravascular use of iodinated contrast media are usually mild to moderate and temporary. However, severe and life-threatening reactions, even fatal ones, have been observed.

Nausea, vomiting, a sensation of pain and a general feeling of warmth are the most common side effects. Other common side effects include: mild swelling of the face, lips, tongue or throat, conjunctivitis, coughing, itching, running nose, sneezing, hives, headache, transient disturbance in breathing, difficulty in breathing, skin redness, and local pain which occurs mainly in the examination of blood vessels, especially if the contrast medium is not injected exactly into the blood vessel. Swelling of the tissue is also possible.

Less commonly reported side effects include: Low blood pressure, difficulty in breathing, swelling of the throat, generally feeling unwell, chills or sweating, dizziness and fainting, transient disturbance in heart beat and heart function, heart attack, low blood pressure, stomach pain, swelling and redness along a vein and a blood clot in a vein. Transient complications relating to the nervous system are uncommon. These include: dizziness, headache, agitation or confusion, loss of memory, disturbed vision, speech and hearing, seizures, tremor, weakness causing loss of movement/paralysis, unpleasant sensitivity to light, temporary blindness, coma and sleepiness.

Other reactions have been reported rarely or very rarely: delayed contrast medium reactions, changes in body temperature and swelling of salivary glands, breathing arrest and build up of fluids in the lungs, severe skin disease (pain, reddening, large blisters, peeling of layers of skin), damage to part of the brain caused by an interruption to its blood supply and temporary kidney failure,

Damage to part of the brain caused by an interruption to its blood supply has been reported on rare occasions.

Other unwanted effects which may occur are: fever, whitening, gagging and a feeling of suffocation, allergic rash, other kinds of skin rash, cramp and whitening eyes.

These reactions, which can occur irrespective of the amount injected and the method of injection may be the first signs of severe allergic circulatory reaction. Severe reactions requiring emergency treatment can occur in the form of a circulatory reaction accompanied by blood vessel dilation and subsequent low blood pressure, increase in heart rate, difficulty in breathing, agitation, confusion and 'turning blue', possibly leading to unconsciousness.

Allergic reactions occur more frequently in patients with an allergic disposition. These reactions can be aggravated in patients taking a type of blood pressure medication known as beta blockers.

Failure to inject UROGRAFIN directly into a vein or artery rarely leads to severe reactions around the site of injection.

Delayed reactions (e.g. fever, rash, flu-like symptoms, joint pain and itchiness) can occasionally occur. Such reactions are more likely to occur if you are receiving the medication interleukin.

If you experience a delayed reaction avoid driving because UROGRAFIN could prevent you from driving safely. Your ability to operate any tools or machines may be impaired.

You may not be able to react rapidly and purposefully in the case of unexpected and suddenly occurring events.

Product description

Storage

The X-ray department or X-ray practice will store UROGRAFIN under conditions advised by the manufacturer. Shelf-life and storage conditions are printed on the bottle.

What it looks like

UROGRAFIN is supplied ready to use as a clear, colourless to pale yellow solution.

Ingredients

Active ingredients

UROGRAFIN contains the substances sodium amidotrizoate and meglumine amidotrizoate (sometimes referred to as sodium diatrizoate and meglumine diatrizoate).

UROGRAFIN 30% contains 0.04g/mL sodium amidotrizoate and 0.26g /mL meglumine amidotrizoate.

UROGRAFIN 76% contains 0.1g/mL sodium amidotrizoate and 0.66g/mL meglumine amidotrizoate.

Inactive ingredients

- sodium calcium edetate
- water for injections

Manufacturer

UROGRAFIN is made in Spain.

Supplier

UROGRAFIN is distributed in New Zealand by:

Bayer New Zealand Limited
3 Argus Place
Hillcrest
North Shore
AUCKLAND 0627

This leaflet was prepared on 29 October 2007.

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