

UROGRAFIN®

(YOU-row-graf-in)

sodium diatrizoate and meglumine diatrizoate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

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

All diagnostic agents have risks and benefits. Your doctor has weighed the risks of you using Urografin against the benefits they expect it will have for 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.

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.

Should you have any questions on the use of Urografin in your X-ray examination, these should be discussed immediately with the staff at the X-ray unit performing the examination.

WHAT UROGRAFIN IS USED FOR

Urografin is an ionic 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 ARE GIVEN UROGRAFIN

When you must not be given it

Do not use Urografin if you have an allergy to:

- any medicine containing sodium diatrizoate or meglumine diatrizoate
- 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 have heart failure or an overactive thyroid gland which are not being adequately treated.

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.

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.

If you are not sure whether you should be given this diagnostic agent, talk to your doctor.

Before you are given it

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

Tell your doctor if you:

- are pregnant or intend to become pregnant
- are breastfeeding or intend to breastfeed. You should discuss with your doctor when to discontinue and resume breastfeeding
- 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 above
- 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)
- take biguanides, one type of medicine used to treat diabetes
- 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, 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)
- take special drugs daily or drink alcohol regularly
- take beta blockers, medicines used to treat high blood pressure or other heart conditions.
- take Interleukin
- have pulmonary emphysema (serious lung disease that makes breathing difficult).

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

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.

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

HOW UROGRAFIN 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 for help.

Urografin 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 Urografin if he/she feels that it is likely to assist the X-ray examination in finding out more about your medical condition.

You should attend for examination fasting but you may drink as usual. Further directions on this will be given by your doctor. 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 administer a laxative (medicines which assist in bowel motion) in the evening, which will be advised by your doctor if necessary.

How much is given

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.

How it is given

Urografin will be injected by the radiologist, assisted by nursing or other X-ray staff.

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.

You will be observed for about 30 minutes after your examination to ensure that you do not suffer a severe reaction to Urografin.

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 follow. The rare and severe side effects noted above can occur regardless of the dosage that is administered.

If in doubt 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 been given too much Urografin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

SIDE EFFECTS

Tell your doctor or radiologist as soon as possible if you do not feel well while you are being given Urografin.

All diagnostic 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 lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

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

- nausea
- vomiting
- a sensation of pain
- a general feeling of warmth
- mild swelling of the face, lips, tongue or throat
- conjunctivitis
- coughing
- itching
- running nose
- sneezing

- hives
- headache
- disturbance in breathing
- difficulty in breathing
- skin redness
- 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

The above list includes the more common side effects of your medicine.

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.

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

- low blood pressure
- difficulty in breathing
- swelling of the throat
- generally feeling unwell
- chills or sweating
- dizziness and fainting
- 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.

The above list includes the less common side effects of your medicine.

Transient complications relating to the nervous system are uncommon. Tell your doctor if you notice any of the following and they worry you:

- 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
- sleepiness

The above list includes the less common side effects of your medicine.

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

- delayed contrast medium reactions
- changes in body temperature
- 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 has been reported on rare occasions
- temporary kidney failure

The above list includes the rare and rarely reported side effects of your diagnostic agent.

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.

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 incipient state of a severe reaction. (See also 'Side effects' above). Tell the doctor immediately if you experience any of these.

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.

AFTER USING UROGRAFIN

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.

PRODUCT DESCRIPTION

What it looks like

Urografin is the brand name for an agent containing the substances sodium diatrizoate and meglumine diatrizoate.

Ingredients

Active ingredients:

- Urografin 30% - contains 40 mg of sodium diatrizoate and 260 mg of meglumine diatrizoate per mL
- Urografin 76% - contains 100 mg of sodium diatrizoate and 660 mg of meglumine diatrizoate per mL

Inactive ingredients:

- sodium calcium edetate
- water for injections

Supplier

Made in Germany for:

Bayer Australia Ltd

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 numbers

- Urografin 30% 10 mL ampoule - AUST R 42161
- Urografin 30% 250 mL bottle - AUST R 42163
- Urografin 76% 50 mL bottle - AUST R 42157
- Urografin 76% 100 mL bottle - AUST R 48496

Not all presentations may be marketed.

Date of preparation

June 2013

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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