

ULTRAVIST®

(UHL-tra-vist)

iopromide

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Ultravist. 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 being given Ultravist against the benefits he/she expects it will have for you.

If you have any concerns about being given Ultravist, ask your doctor.

Keep this leaflet.

You may need to read it again.

WHAT ULTRAVIST IS USED FOR

Ultravist 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, heart, vessels or spinal cord. It can also be used with sensitive computer-assisted X-ray machines (CT scanners) to investigate other parts of your body.

Ultravist is only available in X-ray departments and X-ray practices.

Ask your doctor or the staff at the X-ray department if you have any questions about why Ultravist is being given to you.

It may be given to you for another reason.

BEFORE YOU ARE GIVEN ULTRAVIST

When you must not be given it

You must not be given Ultravist if you have an allergy to:

- iopromide, the active ingredient in Ultravist
- other iodine-containing contrast media (dyes)
- 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 must not be given a second injection of Ultravist less than 48 hours after a first injection into the spine because there is a risk of overdose.

You must not be given Ultravist after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. The staff at the X-ray department will check this for you.

If you are not sure whether you should be given Ultravist, 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 have, or have had, any medical conditions, especially the following:

- overactive thyroid gland or goitre (swelling of the neck caused by enlargement of the thyroid gland)

- asthma
- kidney problems
- heart or blood vessel disease
- diabetes
- any condition affecting your brain or nervous system, particularly if you have ever had a seizure ('fit'), stroke or brain tumour
- cancer of the blood cells (multiple myeloma) or an overproduction of special proteins (paraproteinemia)
- a condition of allergy against parts of your body (autoimmune disease) or a condition in which the muscles become weak and tire easily (myasthenia gravis)
- a rare tumour of the adrenal gland which sits near the kidney and causes high blood pressure (pheochromocytoma)
- dehydration, where your body does not have as much water and fluids as it should; you might feel thirsty, have a dry mouth or your urine might be darker than usual
- blood clots
- anxiety
- very low blood pressure

Also tell your doctor if you are or have ever been addicted to drugs or alcohol.

Your doctor will use this information to decide whether special precautions or a different procedure are needed.

Tell your doctor if you are pregnant, or think you may be pregnant, or if you are breastfeeding.

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

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

Taking other medicines

Tell your doctor if you are taking any medicines, including any that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

Some medicines and Ultravist may interfere with each other. These include:

- beta-blockers, medicines used to treat high blood pressure or other heart conditions
- interleukin-2, a medicine used to treat some forms of cancer
- neuroleptic tranquilisers, medicines used to treat some psychiatric problems
- antidepressants, medicines used to treat depression (low mood)
- metformin, a medicine used to treat diabetes
- diuretics, medicines used to treat high blood pressure and fluid buildup
- any medicine that can have toxic effects on the kidneys

These medicines may be affected by Ultravist or may affect how well it works. You may need to use different amounts of your medicine or to take different medicines. Your doctor will advise you.

Your doctor has more information on medicines to be careful with or to avoid while receiving Ultravist.

HOW ULTRAVIST 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.

How much is given

The actual dose of Ultravist that is right for you will be worked out by the radiologist and will depend on your general health, age, weight and the type of X-ray that is being done.

For most types of X-ray, only a single dose of Ultravist will be required.

How it is given

Ultravist will be injected by the radiologist, assisted by nursing or other X-ray staff. It can be injected into different parts of your body, veins or arteries, depending on the area that needs to be examined.

The speed at which Ultravist is injected, and the length of time until the X-rays are taken will depend on the type of X-ray being done.

If you are given too much (overdose)

As Ultravist is administered by a doctor, overdose is unlikely. The possible outcomes of overdose include effects on the kidneys, heart and lungs.

Immediately tell your doctor or other medical staff if you think that you or anyone else may have been given too much Ultravist. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

AFTER HAVING ULTRAVIST

Things you must do

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

Usually you will need to stay in the X-ray facility for a period of time after receiving Ultravist so that the medical staff can monitor you for side effects.

You will also be advised to take fluids before and after the procedure to help protect your kidneys.

If you are going to have a test on your thyroid, remind your doctor and the medical staff that you have received Ultravist. Ultravist can affect some thyroid tests up to several weeks after receiving it.

Things to be careful of

Avoid driving a car or operating machinery for 24 hours after receiving Ultravist.

This is recommended as a precaution in case you have a delayed reaction to Ultravist.

SIDE EFFECTS

Tell your doctor as soon as possible if you do not feel well whilst receiving or after being given Ultravist.

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:

- headache
- nausea
- vomiting
- dizziness
- flushing
- pain
- reactions at the injection site
- feeling hot
- taste disturbance or loss of taste
- blurry or disturbed vision

The above list includes the more common side effects of Ultravist.

Tell your doctor immediately if you notice any of the following:

- shortness of breath
- wheezing, gasping or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- sneezing, coughing or throat irritation
- watering, sore or inflamed eyes
- seizure ('fit') or loss of consciousness
- paralysis, weakness, problems with speech
- abnormal heart beat
- chest pain or discomfort
- sharp back pain, little or no urine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Some of these symptoms could be the first signs of a severe allergic reaction. Allergic reactions occur more frequently in patients with an allergic disposition.

Severe reactions requiring emergency treatment can occur, causing low blood pressure, increase in heart rate, difficulty breathing, agitation, confusion and "turning blue", possibly leading to unconsciousness.

Your doctor may ask you to stay for observation after your examination so you can be treated immediately if you suffer a severe reaction to Ultravist.

Tell your doctor if you notice anything else that is making you feel unwell

Other side effects not listed above may also occur in some people. Delayed reactions can occasionally occur.

Inactive ingredients:

- trometamol
- sodium calcium edetate
- dilute hydrochloric acid
- 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

Ultravist 240:

- 50 mL - AUST R 15709

Ultravist 300:

- 20 mL - AUST R 47382
- 50 mL - AUST R 15757
- 75 mL - AUST R 48506
- 100 mL - AUST R 48507
- 150 mL* - AUST R 48508

Ultravist 370:

- 20 mL* - AUST R 47383
- 30 mL - AUST R 47384
- 50 mL - AUST R 15681
- 75 mL - AUST R 48498
- 100 mL - AUST R 48499
- 200 mL - AUST R 48501

Date of Preparation

September 2012

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.

*** Pack sizes marked with an asterisk are not registered in New Zealand**

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STORING ULTRAVIST

Storage

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

PRODUCT DESCRIPTION

Ingredients

Active ingredients:

- Ultravist 240: 499 mg iopromide per mL
- Ultravist 300: 623 mg iopromide per mL
- Ultravist 370: 769 mg iopromide per mL