

Consumer Medicine Information

Ultravist[®]

Contrast Imaging Agent

Solution for Infusion - iopromide 240 mg I/mL, 300 mg I/mL & 370 mg I/mL

What is in this leaflet

This leaflet answers some common questions about ULTRAVIST.

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 ULTRAVIST 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.

ULTRAVIST 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 ULTRAVIST is used for

ULTRAVIST is an X-ray contrast medium or X-ray dye that is injected directly into the bloodstream or spinal column whilst X-rays are being taken. All injectable X-ray dyes, including ULTRAVIST, 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 ULTRAVIST is injected into your body it is used by X-ray specialist doctors (radiologists) in one of four ways, depending on the condition that is being investigated in your particular case:

- following injection into an arm vein, ULTRAVIST 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 ULTRAVIST 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
- following injection into an artery or directly into the chambers in the heart, radiologists can directly see the X-ray dye in these areas, and can therefore see

- the shape of the arteries and heart chambers, and can determine whether or not they are blocked or working incorrectly
- following injection into the spinal column, the radiologist can see the X-ray dye in the area of interest

Before you have ULTRAVIST

When you must not take it

You must not be given ULTRAVIST if:

- **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 a known sensitivity or have had a previous reaction to contrast imaging agents**

Before you are given ULTRAVIST

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
- have a known or suspected overactive thyroid gland
- suffer from allergy (e.g. seafood allergy, hay fever, hives) or bronchial asthma.
- suffer from allergy to iodine-containing contrast media, iopromide or any other ingredients listed in this leaflet
- have disturbances of kidney function.
- have heart and circulatory disease
- have very poor general health
- have a circulatory problem in the brain, e.g. history of stroke
- have diabetes
- suffer from brain conditions with seizures or other diseases of the nervous system
- have a swelling of the neck caused by enlargement of the thyroid gland (goitre)
- 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 a history of epilepsy or suspect you have a reduced threshold for seizures

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

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 ULTRAVIST, 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 ULTRAVIST 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-2
- neuroleptics or antidepressants
- radioactive substances for the thyroid gland

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 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 ULTRAVIST.

How to take ULTRAVIST

Before ULTRAVIST is given to you

You will be required to fast (not eat) for 2 hours prior to 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 stomach 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 food that can cause wind, 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. Sometimes it can be appropriate to take a laxative (a medicine to assist bowel motion) in the evening - your doctor will advise you if necessary.

However, in babies and young children fasting should not occur for any long period and laxatives must not be given. You should discuss with your doctor when and what your child should be allowed to eat. Allow your child to drink as normal in the period before the examination.

If you suffer from multiple myeloma, diabetes mellitus requiring treatment, kidney disease, or gout or if you are in a very poor general state of health, you should not restrict your fluid intake before the examination.

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

How to use ULTRAVIST properly

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

ULTRAVIST will be injected by the radiologist, assisted by nursing or other X-ray staff. The radiologist will advise the use of ULTRAVIST 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 ULTRAVIST 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 ULTRAVIST is injected, and the length of time until the X-rays are taken will also depend on the type of X-ray being done. For most types of X-ray only a single dose of ULTRAVIST will be required.

If you are given too much (overdose)

As ULTRAVIST 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 ULTRAVIST. 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 ULTRAVIST.

Tell your doctor if you notice any of the following:

- nausea
- vomiting
- skin redness
- pain
- a feeling of warmth

These are the more common side effects of ULTRAVIST.

Other side effects which may occur are:

- chills
- fever
- sweating
- headache
- dizziness
- blanching
- weakness
- gagging and a feeling of suffocation
- gasping
- a rise or fall of blood pressure
- itching
- allergic rash
- other kinds of skin rash
- swelling
- cramp
- tremor
- sneezing and watering eyes

These reactions may be the first signs of severe allergic circulatory reaction. Allergic reactions occur more frequently in patients with an allergic disposition.

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 breathing, agitation, confusion and "turning blue", possibly leading to unconsciousness.

Temporary kidney failure may occur in rare cases.

After using ULTRAVIST

Delayed reactions can occasionally occur.

Be careful driving or operating machinery until you know how ULTRAVIST affects you.

ULTRAVIST does not generally cause any problems with your ability to drive a car or operate machinery. However as with many other medicines ULTRAVIST may cause dizziness in some people. As a precaution, avoid driving or operating machinery for 24 hours after an examination with ULTRAVIST.

Product description

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 bottle.

What it looks like

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

Ingredients

Active ingredients

ULTRAVIST 240 contains 240 mg iodine per mL of solution, as iopromide 499 mg/mL.
ULTRAVIST 300 contains 300 mg iodine per mL of solution, as iopromide 623 mg/mL.
ULTRAVIST 370 contains 370 mg iodine per mL of solution, as iopromide 769 mg/mL.

Inactive ingredients

- trometamol
- sodium calcium edetate
- dilute hydrochloric acid
- water for injections

Manufacturer

ULTRAVIST is made in Germany.

Supplier

ULTRAVIST is distributed in New Zealand by:

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

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Reference: ULTRAVIST Data Sheet dated 24 August 2007.

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