Package leaflet: information for the patient
Ultravist® 240 mg/ml Solution for injection
Ultravist® 300 mg/ml Solution for injection
Ultravist® 370 mg/ml Solution for injection

iopromide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- if you have any further questions, ask the doctor giving you Ultravist (the radiologist) or the X-ray department staff
- If you get any side effects, talk to your doctor or the X-ray department staff/radiologist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Ultravist is and what it is used for
2. What you need to know before you are given Ultravist
3. How you will be given Ultravist
4. Possible side effects
5. How to store Ultravist
6. Contents of the pack and other information
7. Information for healthcare professionals only

1. What Ultravist is and what it is used for

Ultravist is an injectable contrast medium (a dye) which contains iodine. It is used to clearly show in X-rays the area of your body that your doctor wants to investigate.
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. Ultravist 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. What you need to know before you are given Ultravist

Do not use Ultravist:
- if you are allergic to iodine or iodine containing contrast media or any of the other ingredients of this medicine (listed in Section 6)
- if you have a condition caused by too much thyroid hormone (uncontrolled thyrotoxicosis).

Warnings and precautions
You must tell the X-ray department staff if you have any of the following:
- reduced liver or kidney function
- epilepsy, a history of seizures, or any other condition affecting the brain (CNS disorders)
- a disease of blood vessels in the brain (cerebral arteriosclerosis)
- diabetes mellitus
- a history of gout
- excessive or low urine production
- poor general health
- an overactive thyroid gland (hyperthyroidism) or a swollen neck due to an enlarged thyroid gland (benign nodular goitre)
- a disease of the bone marrow (multiple myeloma)/an increase in the cells which produce antibodies (paraproteinaemia)
- had repetitive and/or large doses of iodinated contrast media like Ultravist
- a history of allergy or a tendency to develop hypersensitivity reactions (for example if you have hay fever, bronchial asthma or eczema)
- heart or blood circulation problems, because in the rare event that you have an allergic reaction, it is more likely to be serious or fatal
- previously had a reaction to any contrast media
- if you have the autoimmune neuromuscular disease leading to muscle weakness (myasthenia gravis)
- history of alcohol or drug dependence or abuse
- if you have any autoimmune disorders
- if you have a history of blood clots
- if you suffer from anxiety

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

Ultravist may affect the results of an **iodine test for thyroid disease**. Always tell your doctor or the laboratory staff that you have been given Ultravist recently.

Children
If your child is newborn, your doctor may monitor their thyroid function as a precaution.

Other medicines and Ultravist
Ultravist should not be mixed with other medicinal products. The use of certain co-medications may result in seizures thus increasing risk of contrast medium related reaction. Please tell the radiologist or X-ray department staff if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is particularly important if:

- you have been treated with a drug called interleukin, as there is a higher chance of getting delayed reactions (e.g. fever, flu-like symptoms, joint pain and itching [pruritis])
- if you have kidney disease and are taking a medicine for diabetes mellitus treatment called metformin as you may need to temporarily stop taking this medicine.
- you are being treated for a thyroid disorder as the efficacy of thyrotropic radioisotopes may be adversely affected
- you have a history of alcoholism.

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

Ultravist with food and drink
Normal diet may be maintained up to two hours prior to the examination. During the last two hours you should refrain from eating.

Do not take any alcohol before your X-ray.

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:

- disease of the bone marrow (multiple myeloma)
- diabetes mellitus
- production of large amounts of urine which is pale in colour (polyuria)
- production of small amounts of urine (oliguria)
- gout

Children
Also, do not reduce the fluid intake of babies, young children, or in someone who is in a very poor general state of health.

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Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the X-ray department staff for advice before taking this medicine. Tell the X-ray department staff if you are pregnant, you think you may be pregnant or are breast feeding. Thyroid problems can sometime occur with babies exposed to Ultravist. The safety of Ultravist for nursed infants has not been investigated. Harm to nursed infants is not likely.

Driving and using machines
There is no known effect on the ability to drive or operate machines. However, you should not drive or operate machinery for 1 hour after the examination as you may have a delayed reaction to Ultravist.

Ultravist contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How you will be given Ultravist
The staff in the X-ray department will decide how much Ultravist is needed for your particular investigation. They will explain how everything works and what position you should lie in on the X-ray table.

The dose of Ultravist varies depending on the investigation and your weight. The dose range is normally between 1 and 200 ml.

You will be asked to stay in the hospital for post procedure observation after your examination. If you develop any symptoms in this time you should return to the X-ray department and tell the X-ray department staff/radiologist.

If you receive more Ultravist 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, this medicine can cause side effects although not everybody gets them.

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

Most common side effects in patients receiving Ultravist are headache, nausea and blood vessel dilation.

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, confusion
- feeling particularly hot or cold, sweating
- paleness or reddening of the skin
- chest pain, palpitations, cramps, tremor
- feeling sick (nausea)

Tell the radiologist or X-ray staff immediately as these may be the first signs of allergic reaction including shock. Your investigation will need to be stopped, and you may need further treatment.

Apart from the symptoms listed above, these are the other side effects of Ultravist, starting with the more common ones:

Common

- **These may affect up to 1 in 10 people**feeling sick (nausea) and vomiting
- headache
- dizziness
- blurred / disturbed vision
- a sensation of pain
- a general feeling of warmth
- problems with your sense of taste (dysgeusia)
- problems with your eyesight
- pain or tightness in the chest / discomfort
- high blood pressure and widening of the blood vessels
- injection site reaction: pain; mild warmth; swelling; inflammation; soft tissue injury and local skin reaction if the injection does not go directly into the blood vessel; feeling hot.

Uncommon

- **These may affect up to 1 in 100 people**hypersensitivity or allergic reaction including itching, wheals on the skin (urticaria), sneezing and coughing
- feeling faint/lightheaded, confused state, restlessness
- coughing, sneezing
- irregular heart beat
- low blood pressure
- swelling or spasm of the voice box (larynx) or throat (pharynx); swelling or fluid in the lungs; swelling of the face, skin, tongue, other mucous membranes (e.g. inside nose or mouth) or other parts of the body; hoarseness, irritation of the throat, asthma, difficulty breathing, spasm of the airways;
- numbness and tingling; decreased feeling or sensitivity, especially in the skin
- swelling beneath the skin (edema)
- sleepiness
- shortness of breath
- abdominal pain
- conjunctivitis; watery eyes

Rare

- **These may affect up to 1 in 1,000 people**anxiety
- palpitations
- cardiac arrest
- a painful reduction of blood supply to the heart (myocardial ischaemia)

Not known
Frequency cannot be estimated from the available data

- excessive thyroid hormone production, thyroid disorder
- reduced blood flow to the brain, blood clot in the brain, stroke, swelling of the brain, convulsion, temporary blindness, loss of consciousness, coma, agitation, amnesia, tremor, speech disorders, weakness / paralysis
- hearing disorders
- heart attack, heart failure, fast or slow heart beats, blue lips, blue or pale skin, shock, palpitations, cyanosis
- shock, abnormal blood clotting events, blood vessel spasm
- accumulation of fluid in the lungs; foreign material entering the lungs (aspiration); the lungs not taking in air properly (respiratory insufficiency)
- difficulty swallowing, salivary gland enlargement, diarrhoea
- bullous conditions (eg. Stevens-Johnson's or Lyell syndrome), rash, redness/blistering of the skin, excessive sweating
- kidney failure and kidney impairment
- feeling unwell, chill, pale skin
- muscle and nerve damage (compartment syndrome)
- body temperature fluctuation
- chemical / aseptic meningitis, neck stiffness, intolerance of bright light, headache
- elevation of pancreatic enzyme levels, inflammation of the pancreas
- loss of sensory/motor function in the lower extremities (paraplegia)
- nerve pain (neuralgia)
- altered mental state (psychosis)

- back pain
- pain in extremities
- urinary disorder
- abnormal EEG

Delayed reactions can 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; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

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5. How to store Ultravist

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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. Keep the vials / bottles in the outer carton and protect from X-rays.

Contrast media must not be used if particulate matter or discolouration is noticed or if the containers are defective.

Once opened, Ultravist should be used within 10 hours.

6. Contents of the pack and other Information

What Ultravist contains
-The active substance is iopromide.
-The other ingredients are sodium calcium edetate (E 385), trometamol, hydrochloric acid (diluted, 10%) and water for injections.

1 ml Ultravist 240 contains 499 mg of Iopromide, equivalent to 240 mg iodine.
1 ml Ultravist 300 contains 623 mg of Iopromide, equivalent to 300 mg iodine.
1ml Ultravist 370 contains 769 mg of Iopromide, equivalent to 370 mg iodine.

What Ultravist looks like and contents of the pack
Ultravist 240 is available in packs of ten 50ml bottles.
Ultravist 300 is available in packs of ten 20ml vials, packs often 50ml, and in single 100ml and 500ml bottles.
Ultravist 370 is available in packs of ten 50ml or 100ml bottles and in a 200ml bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer:
Bayer AG
D-13342 Berlin
Germany

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7. Information for healthcare professionals only

Indications

This medicinal product is for diagnostic use only.

Ultravist 240: For intravascular use and use in body cavities.

Contrast enhancement in computerised tomography (CT), digital subtraction angiography (DSA), intravenous urography, phlebography of the extremities, visualisation of body cavities (e.g. arthrography, hysterosalpingography, fistulography) with the exception of myelography, ventriculography, cisternography.

Ultravist 300: For intravascular use and use in body cavities.

Contrast enhancement in computerised tomography (CT), digital subtraction angiography (DSA), intravenous urography, phlebography of the extremities, venography, arteriography, visualisation of body cavities (e.g. arthrography, hysterosalpingography, fistulography) with the exception of myelography, ventriculography, cisternography.

Ultravist 370: For intravascular use and use in body cavities.

Contrast enhancement in computerised tomography (CT), digital subtraction angiography (DSA), intravenous urography, arteriography and especially angiocardiography, visualisation of body cavities (e.g. arthrography, fistulography) with the exception of myelography, ventriculography, cisternography.

Instructions for use / handling

Vials

The contrast media should be visually inspected prior to use. Do not use if the media is packaged in a defective container, is discoloured or contains particulate matter.

Ultravist should be warmed to body temperature prior to use. The contrast medium solution should not be drawn into the syringe or the infusion bottle attached to the infusion set until immediately before the examination.

The rubber stopper should never be pierced more than once to prevent large amounts of microparticles from the stopper getting into the solution. The use of cannulas with a long tip and a max diameter 18 G is recommended for piercing the stopper and drawing up the contrast medium (dedicated withdrawal cannulas with a lateral aperture, e.g. Nocore-Admix cannulas, are particularly suitable).

Any contrast solution not used in one examination for a given patient is to be discarded.

Large volume containers (only for intravascular administration)

The following applies to the multiple withdrawal of contrast medium from containers of 200 ml or more:

The multiple withdrawal of contrast medium must be done utilizing a device approved for multiple use.

The rubber stopper of the bottle should never be pierced more than once to prevent large amounts of microparticles from the stopper getting into the solution.

The contrast medium must be administered by means of an automatic injector, or by other approved procedures which ensure sterility of the contrast medium.

The tube from the injector to the patient (patient's tube) must be replaced after every patient to avoid cross contamination.

The connecting tubes and all disposable parts of the injector system must be discarded when the infusion bottle is empty or ten hours after first opening the container.

Instructions of the device manufacturer must be followed.

Unused Ultravist in opened containers must be discarded ten hours after first opening the container.