

ULTRAVIST®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given ULTRAVIST?

ULTRAVIST contains the active ingredient iopromide. ULTRAVIST is a contrast agent used during an X-ray examination.

For more information, see Section [1. Why am I given ULTRAVIST?](#) in the full CMI.

2. What should I know before I am given ULTRAVIST?

Do not use if you have ever had an allergic reaction to ULTRAVIST or any of the ingredients listed at the end of the CMI.

Talk to your doctor, radiographer or nurse if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given ULTRAVIST?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ULTRAVIST and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given ULTRAVIST?

ULTRAVIST is injected by the doctor, radiographer or nurse into different parts of your body depending on the area of your body to be examined.

More instructions can be found in Section [4. How am I given ULTRAVIST?](#) in the full CMI.

5. What should I know while receiving ULTRAVIST?

Things you should do	Tell your doctor, radiographer or nurse if you have: <ul style="list-style-type: none">• experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock• experience any asthma symptoms e.g. chest tightening.
Driving or using machines	Avoid driving a car or operating machinery for 24 hours after receiving ULTRAVIST
Laboratory test	ULTRAVIST can affect the results of some thyroid tests up to several weeks after receiving it.
Looking after your medicine	The X-Ray unit will store ULTRAVIST as required by the manufacturer.

For more information, see Section [5. What should I know while receiving ULTRAVIST?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

Serious side effects can include severe allergic reactions, severe asthma, neurological effects (stroke, coma, seizures) and heart attack. Common side effects can include headache, nausea and vasodilatation (feeling hot, flushed or faint).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ULTRAVIST® (UHL-tra-vist)

Active ingredient: *iopromide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ULTRAVIST. **You should also speak to your doctor, radiographer, nurse or pharmacist if you would like further information or if you have any concerns or questions about using ULTRAVIST.**

Where to find information in this leaflet:

- [1. Why am I given ULTRAVIST?](#)
- [2. What should I know before I am given ULTRAVIST?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given ULTRAVIST?](#)
- [5. What should I know while receiving ULTRAVIST?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given ULTRAVIST?

ULTRAVIST contains the active ingredient **iopromide**.

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 also used during an angiogram in a cardiac catheterization procedure to help the doctor visualise the blood vessels in your heart and body using an X-ray machine.

ULTRAVIST can also be used in lumbar myelography to help the doctor visualise the spinal cord in your lower back using an X-ray machine.

2. What should I know before I am given ULTRAVIST?

Warnings

Do not use ULTRAVIST if:

- you are allergic to iopromide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor, radiographer or nurse if you have:

- any allergies to other iodine-containing contrast or any other allergies (e.g. shellfish, hay fever, hives, anaphylaxis)
- asthma
- overactive thyroid gland or goitre (swelling in the neck)
- a neurological condition including seizures, stroke or brain tumour
- a drug or alcohol addiction
- anxiety
- heart or blood vessel disease or blood clots
- kidney problems
- diabetes
- diseases such as multiple myeloma or paraproteinemia or myasthenia gravis
- a rare tumour of the adrenal gland (pheochromocytoma)
- are dehydrated and your body needs more fluids
- very low blood pressure
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

You may be asked to stay in the X-ray department for a period of time after your examination so that the medical staff can monitor you for side effects.

You will also be advised to take fluids before the examination to help protect your kidneys.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

There is no need to stop breastfeeding if you have an examination involving ULTRAVIST.

Use in children

ULTRAVIST is approved for use in adults, adolescents and children including full-term newborns.

3. What if I am taking other medicines?

Tell your doctor, radiographer, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

- are taking metformin used to treat diabetes

- are taking beta-blockers used for high blood pressure or heart conditions
- are taking interleukin-2 used to treat some cancers
- are taking neuroleptic tranquilisers used to treat some psychiatric problems
- are taking antidepressants used to treat depression
- are taking diuretics used to treat high blood pressure or fluid buildup
- any medicine that can have toxic effects on the kidneys

Some medicines may interfere with ULTRAVIST and affect how it works.

If you experience an allergy-like reaction to ULTRAVIST, any treatment given to you may be affected by these medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ULTRAVIST.

4. How am I given ULTRAVIST?

How much to be given

- The dosage of ULTRAVIST is based on your weight and area of your body that will be examined. The doctor or radiographer will calculate the right dose for you.

When ULTRAVIST is given

- ULTRAVIST will be given immediately before or during your examination.

How ULTRAVIST is given

- ULTRAVIST is injected by the doctor or radiographer into different parts of your body depending on the area of your body to be examined.

If you are given too much ULTRAVIST

If you think that you have been given too much ULTRAVIST, ask the doctor, radiographer or nurse. As ULTRAVIST is given by the doctor, radiographer or nurse, overdose is unlikely. If it does happen, a doctor will treat any symptoms that follow.

You should immediately:

- phone the Poisons Information Centre (**by calling Australia: 13 11 26 or New Zealand 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while receiving ULTRAVIST?

Things you should do

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

Call your doctor straight away if you:

- experience any of the severe symptoms of loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock
- experience any asthma symptoms e.g. chest tightening.

Remind any doctor, dentist or pharmacist you visit that you have been given ULTRAVIST.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ULTRAVIST affects you.

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

Laboratory tests

- ULTRAVIST can affect the results of some thyroid tests up to several weeks after receiving it
- Remind your doctor or medical staff after you have received ULTRAVIST.

Looking after your medicine

- The X-ray unit will store ULTRAVIST under the conditions advised by the manufacturer.
- Shelf life and storage conditions are printed on the vial or bottle.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

A high level of excitement, anxiety and pain may increase the risk of side effects or make contrast agent related reactions more intense.

Allergic reaction

Some people may experience symptoms of an allergic reaction such as loss of consciousness or heart attack, increase in heart rate, difficulty breathing, low blood pressure and swelling of the face, lips or tongue leading to severe breathing difficulties and shock.

Allergic reactions occur more frequently in people with a history of allergies to other contrast agents, to foods (e.g.

seafood) or those who suffer from anaphylaxis, hay fever or bronchial asthma.

Most of these reactions occur within one (1) hour of receiving ULTRAVIST. Rarely, some of these reactions may be delayed (up to several days after receiving ULTRAVIST).

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders <ul style="list-style-type: none"> • Nausea • Vomiting • Stomach pain • Diarrhoea Nervous system disorders <ul style="list-style-type: none"> • Headache • Dizziness • Distaste in mouth • Pins and needles sensation or numbness • Restless • Feeling drowsy • Confused General disorders <ul style="list-style-type: none"> • Injection site pain • Feeling hot • Flushing 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
Immune system disorders <ul style="list-style-type: none"> • Experience swelling of the face, eyelids, lips, tongue or other parts of the body • Coughing or throat irritation • Itching or hives • Wheezing, shortness of breath, difficulty breathing, gasping • Gagging, feeling of suffocation • Low blood pressure Nervous system disorders <ul style="list-style-type: none"> • Seizure or convulsion (fit) • Paralysis, weakness, problems with speech • Vasovagal reaction (fainting) Cardiac disorders <ul style="list-style-type: none"> • Heart attack • Chest pain or discomfort • Irregular heartbeat • Abnormal heartbeat (maybe faster) Eye disorders <ul style="list-style-type: none"> • Blurred vision Psychiatric disorders <ul style="list-style-type: none"> • Anxiety Respiratory disorders <ul style="list-style-type: none"> • Difficulty breathing General disorders	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • Injection site reaction • Fluid under skin at injection site • Rash • Little, no or very dark urine 	
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Tell your doctor, radiographer, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration in Australia online at www.tga.gov.au/reporting-problems or in New Zealand <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available in an X-ray unit.

What ULTRAVIST contains

Active ingredient (main ingredient)	Iopromide (contains iodine)
Other ingredients (inactive ingredients)	Trometamol Sodium calcium edetate Dilute hydrochloric acid Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What ULTRAVIST looks like

ULTRAVIST is a clear, colourless to slightly yellow solution for injection and is supplied in glass vials or glass bottles of various sizes.

ULTRAVIST 150:
10 x 50 mL glass bottles – AUST R 15728
10 x 100 mL glass bottles – AUST R 48502
1 x 200 mL glass bottle – AUST R 48503

ULTRAVIST 240:
10 x 10 mL glass vials – AUST R 76434
10 x 50 mL glass bottles – AUST R 15709
10 x 100 mL glass bottles – AUST R 76908

ULTRAVIST 300:
10 x 10 mL glass vials – AUST R 47381
10 x 20 mL glass vial – AUST R 47382
10 x 50 mL glass bottles – AUST R 15757
10 x 75 mL glass bottles – AUST R 48506
10 x 100 mL glass bottles – AUST R 48507
1 x 150 mL glass bottle – AUST R 48508

ULTRAVIST 370:

10 x 20 mL glass vials – AUST R 47383

10 x 30 mL glass vials – AUST R 47384

10 x 50 mL glass bottles – AUST R 15681

10 x 75 mL glass bottles – AUST R 48498

10 x 100 mL glass bottles – AUST R 48499

1 x 150 mL glass bottle – AUST R 48500

1 x 200 mL glass bottle – AUST R 48501

8 x 500 mL glass bottles – AUST R 321040

Not all presentations may be marketed in Australia or New Zealand.

Who distributes ULTRAVIST

Bayer Australia Limited

ABN 22 000 138 714

875 Pacific Highway

Pymble NSW 2073

www.bayer.com.au

Bayer New Zealand Limited

PO Box 2825

Shortland Street

Auckland 1140

Free phone 0800 229 376

This leaflet was prepared in December 2020.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information or on the Medsafe website (www.medsafe.govt.nz) for New Zealand.



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