

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 using ISOVUE®?

ISOVUE® contains the active ingredient Iopamidol. ISOVUE® is used for making blood vessels and other parts of the body visible to X-rays.

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

2. What should I know before I use ISOVUE®?

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

Talk to your doctor 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 use ISOVUE®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ISOVUE® 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 do I use ISOVUE®?

- ISOVUE® is given as an injection before the X-ray procedure. Your radiologist will determine the correct dose for you.

More instructions can be found in Section [4. How do I use ISOVUE®?](#) in the full CMI.

5. What should I know while using ISOVUE®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ISOVUE®.• Tell your radiologist, doctor or pharmacist if you are taking any other medicines, especially anti-diabetic medicines, metformin (Diabex®, Diaformin® or Glucophage®), buformin or phenformin.
Driving or using machines	<ul style="list-style-type: none">• As delayed reactions to iodine-containing dyes may occur, do not drive a vehicle or operate machinery for at least 24 hours after receiving the injection of ISOVUE®.

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

6. Are there any side effects?

Less serious side effects of ISOVUE® may include: flushing, hives or rash, skin blisters, muscle pain or weakness, involuntary movements, leg weakness, sweating, fever, chills, very low body temperature, injection-site reactions, chest tightness, feeling unwell, tingling or numbness, wheezing or coughing, difficulty swallowing, difficulty urinating, vivid dreams, drowsiness, unusual bruising, reduced sensitivity, back or leg pain, shoulder pain, cold extremities, vision disturbances, eye irritation or swelling, conjunctivitis, nausea, vomiting, abdominal pain, loss of appetite, diarrhoea, heartburn, altered taste, nasal congestion or runny nose, sneezing, facial pressure, dry mouth, sore throat, palpitations or fast heartbeat, headache, dizziness, emotional stress.

Serious side effects may include: allergic reactions, bluish skin, kidney problems, neurological disturbances, blindness, dilated pupils, abnormal eye movements, rectal bleeding, swallowing difficulty with tongue swelling/redness, chest pain from angina, blood pressure changes, abnormal heart rhythms, circulatory collapse, heart attack, vein inflammation, coagulation problems, facial or throat swelling, faintness, restlessness, seizures, confusion, meningitis or meningitis-like reactions, agitation, memory loss, poor coordination, hallucinations, severe facial nerve pain, tinnitus, shortness of breath, asthma, fluid in the lungs, swelling of the voice box, hypothyroidism.

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.

ISOVUE®

Active ingredient(s): [iopamidol]

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using ISOVUE®?

ISOVUE® contains the active ingredient iopamidol.

ISOVUE® is an iodine-containing dye, called a “contrast medium”. ISOVUE® is given as an injection before the X-ray procedure.

ISOVUE® is used for making blood vessels and other parts of the body visible to X-rays.

2. What should I know before I use ISOVUE®?

Warnings

Do not use ISOVUE® if:

- you are allergic to iopamidol, or any of the ingredients listed at the end of this leaflet, or any other iodine-containing contrast media.
- Always check the ingredients to make sure you can use this medicine.
- You suffer from:
 - A condition affecting the thyroid gland
 - Decompensated cardiac failure or insufficiency
 - A recent stroke or heart attack
 - Any infection or open injury in or near the area to be examined
 - An infection and ISOVUE® is to be injected into your spinal cord
- If ISOVUE® is to be injected into your spinal cord within 48 hours of the first injection

Check with your radiologist or doctor if you:

- have any other medical conditions:
 - heart disease or disease of the blood vessels
 - respiratory conditions
 - kidney disease or urinary problems
 - any disorder or injuries affecting the brain or nervous system
 - multiple myeloma or myelomatosis
 - diabetes
 - gout
 - liver disease
 - phaeochromocytoma
 - sickle cell disease
 - alcoholism
 - abscesses
 - homocystinuria
- 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?](#)

Pregnancy and breastfeeding

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

It is not known if ISOVUE® harms the developing baby. ISOVUE® should therefore be used during pregnancy **only** if your doctor decides it is essential for your health. If you received contrast media whilst pregnant, your baby may be given a test for hypothyroidism in the period shortly after birth.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if ISOVUE® passes into human milk. Stop breastfeeding your baby before you have an injection of ISOVUE® and do not start breastfeeding again until you have checked with your doctor that it is safe to do so.

Children

- In children, ISOVUE® is injected only into the blood vessels.

Elderly

- The elderly require special care when receiving an injection of ISOVUE®

3. What if I am taking other medicines?

Tell your doctor 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.

In particular, you should tell your radiologist or doctor if you are taking any of the following:

- antidepressants
- anti-nauseants
- antihistamines
- drugs that act on the central nervous system
- anti-diabetic medicines metformin, buformin or phenformin

Some medicines may interfere with ISOVUE® and affect how it works.

The anti-diabetic medicines, metformin (Diabex®, Diaformin® or Glucophage®), buformin (not available in Australia) or phenformin (not available in Australia) may interact with ISOVUE® and cause harm to the kidneys. Check with your doctor or pharmacist which anti-diabetic medicine or medicines you are taking, and, if you are taking metformin, buformin or phenformin, stop taking these medicines at least 48 hours before your X-ray and do not start taking them again until at least 48 hours after your X-ray.

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

4. How do I use ISOVUE®?

How much to use

- ISOVUE® is given as an injection before the X-ray procedure. Your radiologist will determine the correct dose for you.

If you use too much ISOVUE®

In the unlikely event of your receiving an overdose, your radiologist will know how to treat you.

5. What should I know while using ISOVUE®?

Call your doctor straight away if you:

- develop pain at the injection site, if you are not feeling well or experiencing side effects, after receiving an injection of ISOVUE®, during the X-ray procedure or afterwards.
- phone the Poisons Information Centre on **13 11 26**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Driving or using machines

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

As delayed reactions to iodine-containing dyes may occur, do not drive a vehicle or operate machinery for at least 24 hours after receiving the injection of ISOVUE®.

Drinking alcohol

Tell your doctor if you drink alcohol.

Isovue® should be administered with caution in patients with chronic alcoholism.

Looking after your medicine

- You will not normally be required to store ISOVUE®. It will usually be kept by your radiologist or in the radiology or pharmacy department of the hospital where you are having the X-ray.
- The expiry date of ISOVUE® can be found on the label of the ampoule or vial.
- ISOVUE® must be stored below 25°C and protected from light.

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.

Less serious side effects

Less serious side effects	What to do
<p>General:</p> <ul style="list-style-type: none"> • Flushing or hot flushes • Urticaria (hives, itchy rash, pink itchy swellings on the skin) • Skin blisters • Muscle cramps, tenderness, weakness or aching muscles • Involuntary movements • Weakness or paralysis of both legs and sometimes part of the lower body • Sweating or clammy skin • Fever or high temperature • Chills or shivering • Extremely low body temperature • Reaction and/or pain at the site of injection • Tightness and/or pain in the chest • Anaphylactoid reaction (resembles an anaphylactic reaction) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • Bluish discolouration of the skin • Feeling unwell • Tingling or numbness of the hands or feet (“pins and needles”) • Wheezing or coughing • Difficulty in swallowing • Difficulty in passing urine • Acute renal failure • Abnormal function of the kidneys • Disease of the brain • Vivid dreams • Sleepiness/drowsiness • Unusual bleeding or bruising under the skin • Decreased feeling or sensitivity • Backache or lower back irritation • Leg or sciatic-type pain (from buttock into the leg) • Shoulder pain • Cold extremities <p>Eyes:</p> <ul style="list-style-type: none"> • Disturbances of vision • Swelling around the eyes • Itchy eyes • Uncomfortable sensitivity to light • Conjunctivitis (discharge with itching of the eyes and crusty eyelids) • Abnormal production of tears <p>Gastrointestinal tract:</p> <ul style="list-style-type: none"> • Nausea (feeling sick) • Vomiting • Abdominal discomfort or pain • Loss of appetite • Diarrhoea • Heartburn <p>Nose, mouth and throat:</p> <ul style="list-style-type: none"> • Altered taste sensation • Nasal congestion • Runny or blocked nose • Sneezing • Facial pressure or pain • Dry mouth • Sore throat <p>Heart and blood circulation:</p> <ul style="list-style-type: none"> • Palpitation (fast or irregular heart beat)/Fast beat <p>Nervous system:</p> <ul style="list-style-type: none"> • Sensation of heat/pain • Headache • Dizziness/ Light-headedness • Emotional stress 	
--	--

Serious side effects

Serious side effects	What to do
<p>General</p> <ul style="list-style-type: none"> • Anaphylactoid reaction (resembles an anaphylactic reaction) • Acute renal failure • Abnormal function of the kidneys • Disease of the brain • Unusual bleeding or bruising under the skin • Decreased feeling or sensitivity <p>Eyes:</p> <ul style="list-style-type: none"> • Blindness • Dilated pupils • Involuntary upward movement of the eyes <p>Gastrointestinal tract:</p> <ul style="list-style-type: none"> • Bleeding from the rectum • Discomfort when swallowing/ Swollen red, sore tongue/ <p>Heart and blood circulation:</p> <ul style="list-style-type: none"> • Extra heart beats • Angina (chest pain or feeling of tightness, pressure or heaviness in the chest) • Low blood pressure • High blood pressure • Slow heart beat • ECG (record of electrical activity in the heart) changes • Changes in the output of the heart • Changes in factors affecting the force and flow of circulating blood • Circulatory collapse (collapse of the circulation of the blood) • Changes in the rhythm or rate of the heart beat • Heart attack • Swelling and redness along a vein which is extremely tender when touched • Disseminated intravascular coagulation (a condition of the clotting mechanism of the blood, in response to disease or injury, initially causing clotting and later bleeding) • Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing 	<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>

Nervous system:

- Faintness
- Restlessness
- EEG (record of electrical activity in the brain) changes
- Convulsions (fits, seizures or convulsions)
- Confusion/Vivid dream
- Meningismus (irritation of the brain and spinal cord)
- Meningitis (infection or swelling of the membranes covering the brain and spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light) and meningitis-like reaction
- Meningeal irritation (irritation of the membranes that cover the brain and spinal cord)
- Agitation
- Loss of memory
- Abnormal co-ordination
- Hallucinations
- Temporary disturbances in brain function similar to epileptic fits
- Severe stabbing or throbbing pain along one or more nerves in the face
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears
- Sleepiness/drowsiness
- Involuntary movements
- Weakness or paralysis of both legs and sometimes part of the lower body
- Fever or high temperature
- Extremely low body temperature

Respiration:

- Difficulty in breathing/ Shortness of breath
- Asthma
- Build-up of fluid in the lungs causing breathlessness which may be very severe and usually worsens on lying down
- Swelling of the voice box, tongue and face

Endocrine system:

- Hypothyroidism (i.e. condition when thyroid gland does not produce enough thyroid hormones to meet the needs of the body)

Tell your doctor 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 online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What ISOVUE® contains

Active ingredient (main ingredient)	Iopamidol
Other ingredients (inactive ingredients)	Trometamol Sodium calciumedetate Hydrochloric acid or sodium hydroxide (to adjust pH)

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

What ISOVUE® looks like

ISOVUE® is a clear, colourless to pale yellow liquid contained in a glass ampoule or vial.

ISOVUE® 300 INJECTION (equivalent to 300 mg iodine/mL)

Each mL of **ISOVUE® 300** contains 612 mg of iopamidol. It is available in the following pack sizes:

- 50 mL vial (AUST R 47068)

- 100 mL vial (AUST R 47069)

ISOVUE® 370 INJECTION (equivalent to 370 mg iodine/mL)

Each mL of **ISOVUE® 370** contains 755 mg of iopamidol. It is available in the following pack sizes:

- 50 mL vial (AUST R 47070)

- 100 mL vial (AUST R 47071)

- 200 mL vial (AUST R 47072)

Who distributes ISOVUE®

Sponsor:

Bracco Pty. Ltd.

14 Allambie Avenue, East Lindfield

NSW 2070

ealang57@gmail.com

Distributed by:

Regional Health Care Products Group

Medi-Consumables Pty. Ltd.

3-11 Primrose Avenue

ROSEBERY NSW 2018, AUSTRALIA

Regional Health Limited

P O Box 101-140

North Shore Mail Centre

Auckland, New Zealand

This leaflet was prepared in December 2025.