

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers common questions about ISOVUE®.

It does not contain all the available information.

It does not take the place of talking to your radiologist (the specialist doctor who does X-rays), doctor or pharmacist. All preparations of this type have risks and benefits. Your radiologist and/or your doctor have weighed the risks of your receiving ISOVUE® against the benefits they expect it will have for you.

If you have any concerns about being given this preparation, ask your radiologist, doctor or pharmacist.

Keep this leaflet. You may need to read it again.

WHAT IS ISOVUE®

ISOVUE® is the trade name for iopamidol, an iodine-containing dye, called a "contrast medium". It comes as a solution for injection in ampoules or vials.

WHAT ISOVUE® IS USED FOR AND HOW IT WORKS

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

Injection of ISOVUE® into the blood vessels dyes the blood vessels through which the blood flows. This allows the blood vessels in that area to be seen on an X-ray.

Injection of ISOVUE® into the spinal cord allows the nerves within the spine to be seen on an X-ray. The resulting X-ray photographs may help your doctor to diagnose your illness or problem.

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

BEFORE YOU HAVE AN INJECTION OF ISOVUE®

You must not have an injection of ISOVUE®:

- If you are **allergic to iopamidol or to any of the ingredients in ISOVUE®** (listed under "PRODUCT DESCRIPTION, What it looks like", at the end of this leaflet) or to any other iodine-containing contrast media. There have been some cases of severe and life-threatening reactions occurring with iodine-containing contrast media. The possibility of such reactions occurring with ISOVUE® therefore cannot be ruled out. Your radiologist has appropriate medicines and equipment on hand to treat you, in the unlikely event that you should experience a reaction to ISOVUE®.
- If you suffer, or have suffered from a condition affecting the **thyroid gland**.
- If you suffer from **decompensated cardiac failure or insufficiency** (a condition of heart failure where the heart is unable to provide enough blood to all the cells of the body).
- If you have recently suffered from a **stroke or heart attack**.

- If you are suffering from any **infection or open injury in or near the area to be examined**.
- If you are suffering from 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 of ISOVUE into your spinal cord**.

Before having an injection of ISOVUE®, tell your doctor or radiologist

- If you are **allergic** to iopamidol or to any of the ingredients in ISOVUE® or to any other iodine-containing contrast media.
- If you suffer from, or have suffered from **any allergy or allergies**.
- If you are suffering from any **infection or open injury in or near the area to be examined**.
- If you are suffering from an **infection and ISOVUE® is to be injected into your spinal cord**.
- If you are to receive an **injection of ISOVUE® into the spinal cord within 48 hours of your first injection of ISOVUE® into the spinal cord**.
- If you are going to have an iodine test for thyroid disease
- If you are **pregnant or intend becoming pregnant**. It is not known if ISOVUE® harms the developing baby. X-rays can be harmful to unborn babies. ISOVUE® should therefore be used during pregnancy **only** if your doctor decides it is essential for your health. Be sure to discuss this thoroughly with your doctor and/or your radiologist. If you received contrast media whilst pregnant your baby may be given a test for hypothyroidism in the period shortly after birth.
- If you are **breast-feeding or planning to breast-feed**. It is not known if ISOVUE® passes into human milk. Because many substances do pass into human milk, stop breastfeeding your baby before you have an injection of ISOVUE®, feed the baby with formula milk and do not start breastfeeding again until you have checked with your doctor that it is safe to do so.
- If you suffer from, or have suffered from **heart disease or disease of the blood vessels**, including stroke or heart attack, decompensated cardiac failure or insufficiency (a condition of heart failure where the heart is unable to provide enough blood to all the cells of the body), uncontrolled cardiac arrhythmia (changes in the rhythm or rate of the heart beat), advanced disease of the blood vessels, advanced atherosclerosis (thickening and hardening of the arteries), Buerger's disease or thromboangitis obliterans (a condition in which swelling and clotting of the small and medium blood vessels occurs), poor blood supply to a body organ or part

associated with infection, right ventricular failure (failure of the right ventricle [chamber] of the heart to pump blood strongly enough to the lungs), pulmonary hypertension (abnormally high pressure within the arteries and veins of the lungs), bruises or bruising, heart failure, hypotension (low blood pressure), hypertension (high blood pressure).

- If you suffer from **respiratory conditions** (conditions affecting the lungs or breathing), including asthma, pulmonary emphysema (a disease of the lungs, marked by overly large air sacs), stenotic pulmonary vascular beds (narrowed blood vessels in the lungs).
- If you suffer from **kidney disease** or urinary problems, including excessive production of urine or decreased production of urine.
- If you suffer from **any disorder or injuries affecting your brain or nervous system**, for example, stroke, subarachnoid haemorrhage (bleeding into a fluid-filled space between the layers of membranes at the base of the brain near the spine), bleeding inside the skull or brain, increased intracranial pressure (pressure inside the skull) or suspected intracranial tumour (cancer within the skull), multiple sclerosis (MS), migraine, cerebral arteriosclerosis (hardening, thickening or loss of elasticity in the walls of the arteries in the brain), cerebral spasmodic conditions (brain spasms), epilepsy, fits, seizures or convulsions (if you are on anti-convulsant medication [medicines used to treat epilepsy or fits] for these conditions, your doctor will probably advise you to continue with it, before and after the X-ray, and will probably keep you under observation for at least 48 hours after the X-ray).
- If you suffer from multiple myeloma or myelomatosis (a cancer of the bone marrow),
- If you are dehydrated,
- If you suffer from juvenile-type **diabetes** or diabetes of long standing.
- If you are **diabetic** and are being treated with metformin (Diabex®, Diaformin® or Glucophage®), buformin (not available in Australia) or phenformin (not available in Australia), you must not take any of these medicines for 48 hours before, and 48 hours after your X-ray, to avoid harming your 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. Also, on making the appointment for the X-ray, remember to tell your radiologist (the specialist X-ray doctor) and/or radiographer (the radiologist's assistant who may actually take the X-rays) that you are taking these medicines but that you will not be taking them for at least 48 hours before, or 48 hours after

the X-ray. Mention it again to the radiologist and/or the radiographer when you arrive for your X-ray appointment. If you are at all unsure about this or what to do, discuss first with your doctor.

- If you have gout (a disorder of uric acid production with painful swelling of joints),
- If you are in poor general health, run down or debilitated,
- If you have liver disease,
- If you suffer from pheochromocytoma (a tumour of the adrenal gland that causes excess release of adrenaline, leading to high blood pressure and other problems),
- If you suffer from sickle cell disease (a disease of the red blood cells),
- If you are an alcoholic,
- If you suffer from an abscess or abscesses,
- If you suffer from homocystinuria (a rare disease characterised by the abnormal presence of homocystine in the blood and urine),
- about all medical conditions you have, or have had in the past.

Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription medicines and those bought without a prescription from a pharmacy, supermarket, health food store or elsewhere.

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

Antidepressants (medicines used for the treatment of depression)

Check with your pharmacist if you are not sure if you are taking an antidepressant.

Antinauseants (medicines used for the treatment of nausea)

Check with your pharmacist if you are not sure if you are taking an antinauseant.

Antihistamines (medicines used for the treatment of allergies)

Check with your pharmacist if you are not sure if you are taking an antihistamine.

Drugs that act on the central nervous system such as tranquillisers, sedatives etc.

Check with your pharmacist if you are not sure if you are taking any such drugs.

The anti-diabetic medicines metformin, buformin or phenformin

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. If you are diabetic and are taking any of these medicines, follow the instructions under "Tell your doctor if you are diabetic" of "BEFORE YOU HAVE AN INJECTION OF ISOVUE®", above.

Check with your pharmacist if you are not sure which antidiabetic medicine you are taking.

HOW ISOVUE® IS USED

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

What if you receive an overdose?

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

SIDE EFFECTS

All medicines have some risks associated with their use. ISOVUE® is a special type of contrast medium, called a non-ionic contrast medium. The non-ionic contrast media are newer and there is less chance of unwanted side effects occurring with them, than with the older ionic media.

ISOVUE® may cause unwanted side effects in some people. Usually the side effects are mild and only last a short time. However, they can be serious and may require medical treatment in some cases. Side-effects reported to date include:

Severe and life-threatening reactions.

There have been some cases of severe and life-threatening reactions occurring with iodine-containing contrast media. The possibility of such reactions occurring with ISOVUE® therefore cannot be ruled out. Your radiologist has appropriate medicines and equipment on hand to treat you, in the unlikely event that you should experience a reaction to ISOVUE®.

Side effects affecting the heart and blood circulation.

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; fast 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); dangerously fast heart beat; changes in the rhythm or rate of the heart beat; palpitations (fast or irregular heart beats); 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.

Side effects affecting the nervous system.

Sensation of heat/pain; headache; dizziness; faintness; restlessness; EEG (record of electrical activity in the brain) changes; convulsions (fits, seizures or convulsions); confusion; coma; 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); meningitis-like reaction (a reaction with similar symptoms to meningitis); meningeal irritation (irritation of the membranes that cover the brain and spinal cord); agitation; loss of memory; abnormal co-ordination; emotional stress; hallucinations (seeing, feeling or hearing things that are not there); light-headedness; cold extremities; temporary disturbances in brain function similar to epileptic fits, seizures or convulsions; severe stabbing or throbbing pain along one or more nerves in the face; buzzing, hissing, whistling, ringing or other persistent noise in the ears; sweating; drowsiness.

Side effects affecting respiration. Difficulty in breathing; wheezing or coughing; shortness of breath; asthma; build-up of fluid in the lungs causing breathlessness which may be very severe and usually worsens on lying down.

Side effects affecting the endocrine system (ie organs that produce hormones):

hypothyroidism (ie condition when thyroid gland does not produce enough thyroid hormones to meet the needs of the body).

Side effects affecting the eyes. Disturbances of vision; swelling around the eyes; blindness; itchy eyes; dilated pupils; uncomfortable sensitivity to light; conjunctivitis (discharge with itching of the eyes and crusty eyelids); abnormal production of tears; involuntary upward movement of the eyes.

General side effects. Flushing; urticaria (hives, itchy rash, pink itchy swellings on the skin); itching; skin rash; skin blisters filled with fluid; muscle cramps; aching muscles; muscle tenderness or weakness, not caused by exercise; involuntary movements; weakness or paralysis of both legs and sometimes part of the lower body; sweating; fever; chills; shivering; violent attacks of shivering that may come with chills and fever; extremely low body temperature; cold or clammy skin; reaction and/or pain at the site of the injection; tightness and/or pain in the chest; anaphylactoid reaction (resembles an anaphylactic reaction [sudden life-threatening reaction, with signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing]); bluish discoloration of the skin; generally feeling unwell; tingling or numbness of the hands or feet or "pins and needles"; coughing; difficulty in swallowing; difficulty in passing urine; acute renal failure (kidney disease where you pass little or no urine, other symptoms include drowsiness, nausea, vomiting and breathlessness); abnormal function of the kidneys; disease of the brain; vivid dreams; sleepiness/drowsiness; unusual bleeding or bruising under the skin, visible through the skin as purple or brown spots; decreased feeling or sensitivity, especially in the skin; backache; leg or sciatic-type pain (pain from the buttock into the leg); fever or high temperature; muscle weakness; hot flushes; lower back irritation; shoulder pain; leg cramps.

Side effects affecting the gastrointestinal tract.

Nausea (feeling sick), vomiting; abdominal discomfort or pain; loss of appetite; diarrhoea; bleeding from the rectum; heartburn.

Side effects affecting the nose, mouth and throat.

Altered taste sensation; nasal congestion, runny or blocked nose, sneezing, facial pressure or pain; swelling of the voice box, tongue, face; swollen red, sore tongue; dry mouth; sore throat and discomfort when swallowing.

Some people may experience other side effects after an injection of ISOVUE®.

Tell the radiologist, radiographer or doctor immediately, if pain develops 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.

Effect on ability to drive or operate machinery

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®**.

FURTHER INFORMATION

Your radiologist keeps supplies of **ISOVUE®** and will inject you with it during the X-ray procedure. The elderly require special care when receiving an injection of **ISOVUE®**.

STORAGE CONDITIONS

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.

PRODUCT DESCRIPTION

What it looks like

ISOVUE® is a clear, colourless to pale yellow liquid contained in a glass ampoule or vial. Iopamidol is the active ingredient of **ISOVUE®**. **ISOVUE®** also contains the following inactive ingredients: trometamol, sodium calciumedetate, hydrochloric acid or sodium hydroxide (to adjust pH).

Each strength and pack size of **ISOVUE®** has an Australian Registration number (AUST R) on the label, as shown below:

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)

WHERE TO GO FOR FURTHER INFORMATION

The information provided in this leaflet is only a summary and does not cover all the information known about **ISOVUE®**. More detailed information is available from your doctor, radiologist or pharmacist. If you have any concerns or queries or experience any difficulties before, during or after taking **ISOVUE®**, ask your radiologist, doctor or pharmacist.

SPONSOR

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