

# IOMERON®

## 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 IOMERON®?

IOMERON® contains the active ingredient iomeprol. IOMERON® is used to make blood vessels and other parts of the body visible to X-rays.

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

### 2. What should I know before I use IOMERON®?

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

**Talk to your radiologist or 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 IOMERON®?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with IOMERON® 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 IOMERON®?

- Your radiologist/doctor will inject the correct amount of IOMERON® into a blood vessel or body cavity, before taking the X-ray photographs.

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

### 5. What should I know while using IOMERON®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using IOMERON®.</li><li>Tell your radiologist, doctor or pharmacist if you are taking any other medicines, such as neuroleptics, antidepressants, anticonvulsants, nephrotoxic drugs, corticosteroids or diabetic drugs like metformin.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Do not drive a vehicle or operate machinery for at least 24 hours after receiving the injection of IOMERON® as delayed reactions to iodine-containing dyes may occur within this period.</li></ul>

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

### 6. Are there any side effects?

Less serious side effects may include: flushing, injection-site pain/bleeding/swelling, itching, rash, sweating, weakness, fever, feeling unwell, tingling or numbness of skin, excessive hairiness, chills, swelling, fatigue, chest pain, back pain, low muscle strength, muscle stiffness, nervousness, skin discolouration, drowsiness, urinary incontinence, cough, limb numbness or weakness, palpitations, abnormal vision, watery or swollen eyes, eye pain, nausea, vomiting, diarrhoea, burping, abdominal pain, runny or blocked nose, dry mouth, increased salivation, altered taste, lip inflammation, sinus pressure/fullness, heat sensation, headache, dizziness, mood swings.

Serious side effects may include: life-threatening allergic reaction, reduced urine output, protein in urine, faecal incontinence, paralysis, swollen/red/sore tongue, sore throat or painful swallowing, heart attack, abnormal heart rate or rhythm, ECG changes, high or low blood pressure, collapse, fainting, shock, confusion, CNS disturbances (tremor, muscle spasms, loss of consciousness, language impairment, loss of smell or taste, seizures, coma), difficulty breathing, asthma. 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.

# IOMERON®

Active ingredient(s): *Iomeprol*

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I using IOMERON®?

IOMERON® contains the active ingredient **iomeprol**. IOMERON® is an iodine-containing dye, called a “contrast medium” and is injected into blood vessels or body cavities to make blood vessels and other parts of the body visible to X-rays.

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

## 2. What should I know before I use IOMERON®?

### Warnings

**Do not use IOMERON® if:**

- you are allergic to iomeprol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you suffer from multiple myeloma or Waldenstroem's paraproteinaemia (a disorder of the immuno-globulins -cells involved in the body's natural ability to fight disease).
- you suffer from kidney disease or a combination of severe liver and kidney disease.
- you underwent a myelography procedure during the last 48 hours.

**Check with your doctor if you:**

- have any other medical conditions such as:
  - asthma
  - hay fever or food allergy

- overactive thyroid gland or goitre
  - diabetes and being treated with metformin (Diabex, Diaformin or Glucophage)
  - pheochromocytoma
  - heart disease or problems with your heart, especially if you are elderly
  - increased blood pressure
  - any disorder or injuries affecting your brain or nervous system
  - alcoholism
  - addiction to, or dependence on drugs or medicines
  - inflammation of the female sex organs
  - myasthenia gravis
  - sickle-cell disease
- 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.

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.

Because many substances do pass into human breast milk, stop breastfeeding your baby before you have an injection of IOMERON®, 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.

### Children

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

## 3. What if I am taking other medicines?

Tell your radiologist, 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.

**Some medicines may interfere with IOMERON® and affect how it works:**

- Neuroleptics (medicines used for the treatment of some mental disorders – sometimes also called major tranquillisers).

- Antidepressants (medicines used for the treatment of depression).
- Anticonvulsants (any medicine used for the treatment of epilepsy or fits).
- Certain medicines used to treat diabetes, such as metformin.
- Nephrotoxic drugs (medicines which can have a side effect of damaging the kidneys in certain doses and under certain conditions).
- Corticosteroids (a class of steroid hormones) may promote and affect the signs and symptoms of arachnoiditis (inflammation of arachnoid).

**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 IOMERON®.**

**Your doctor may ask you not to take certain medicines for 48 hours before receiving an injection of IOMERON®.**

## 4. How do I use IOMERON®?

### How much to use

- The strength and amount of IOMERON® you will be given depends upon the parts of your body which are being examined and your body weight. Your radiologist/doctor will inject the correct amount of IOMERON® into a blood vessel or body cavity, before taking the X-ray photographs.
- You will probably be observed for at least 30 minutes after the X-ray.

### When to use IOMERON®

- IOMERON® is used to make blood vessels and other parts of the body visible to x-rays, so that x-ray photographs can be taken.
- IOMERON® will be injected into a blood vessel or any other parts of the body by your radiologist/doctor.

### If you use too much IOMERON®

You will be given IOMERON® by injection in a hospital environment so it is extremely unlikely you will be given too much.

However, if you experience any side effects after being given IOMERON® tell your radiologist or doctor immediately. Your radiologist or doctor will know how to treat you.

If you think that you have been given too much IOMERON®, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.**

## 5. What should I know while using IOMERON®?

### Things you should do

Your radiologist or doctor will advise you what to do before, during and after your procedure.

You should have plenty to drink and can eat normally on the day of your x-ray up to two hours before receiving an injection of IOMERON®.

### Driving or using machines

**Do not drive a vehicle or operate machinery for at least 24 hours after receiving the injection of IOMERON® as delayed reactions to iodine-containing dyes may occur within this period.**

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may increase the risk of seizure when contrast media such as IOMERON® is administered, so caution must be exercised.

### Looking after your medicine

- You will not normally be required to store IOMERON®. 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.
- Your radiologist should store this product below 25°C and protect it from light. It is advisable to store the product out of reach of ionising radiation.

## 6. Are there any side effects?

**Tell the radiologist/doctor immediately if you are not feeling well after receiving an injection of IOMERON®, during the x-ray procedure and afterwards.**

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
<b>General:</b> <ul style="list-style-type: none"> <li>• Flushing</li> <li>• Pain, bleeding and swelling at the site of injection</li> <li>• Itching</li> <li>• Rash</li> <li>• Sweating</li> <li>• Unusual weakness</li> <li>• Fever</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• Generally feeling unwell</li> <li>• Sensation of tingling, prickling or numbness of the skin</li> <li>• Excessive hairiness</li> <li>• Chills</li> <li>• Swelling</li> <li>• Fatigue</li> <li>• Chest pain</li> <li>• Back pain</li> <li>• Low muscle strength</li> <li>• Muscle stiffness</li> <li>• Nervousness</li> <li>• Skin discolouration</li> <li>• Drowsiness</li> <li>• Urinary incontinence</li> <li>• Coughing</li> <li>• Numbness or weakness of arms and legs</li> <li>• Palpitation</li> </ul> <p><b>Eyes:</b></p> <ul style="list-style-type: none"> <li>• Abnormal vision</li> <li>• Swollen runny eyes</li> <li>• Eye pain</li> </ul> <p><b>Gastrointestinal tract:</b></p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Diarrhoea</li> <li>• Burping</li> <li>• Abdominal pain</li> </ul> <p><b>Nose, mouth and throat:</b></p> <ul style="list-style-type: none"> <li>• Runny or blocked nose</li> <li>• Dry mouth</li> <li>• Increased salivation</li> <li>• Disturbance of taste sensation</li> <li>• Inflammation of the lip</li> <li>• feeling of tension or fullness in the nose and behind the ears (sinusitis)</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• Heat sensation</li> <li>• Headache</li> <li>• Dizziness</li> <li>• Mood swings</li> </ul>	<p><b>[Insert appropriate action]</b></p>
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<ul style="list-style-type: none"> <li>• Swollen, red, sore tongue</li> <li>• Sore throat and discomfort when swallowing</li> </ul> <p><b>Heart and blood circulation:</b></p> <ul style="list-style-type: none"> <li>• Heart attack</li> <li>• Changes in heart rate or heart beat (fast, slow or irregular)</li> <li>• ECG change</li> <li>• High or low blood pressure</li> <li>• Collapse due to very low blood pressure</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• Fainting</li> <li>• Shock</li> <li>• Confusion</li> <li>• CNS disturbances such as tremor, muscular spasms, loss of consciousness, loss of ability to comprehend language, loss of smell, taste, convulsive seizures and coma</li> </ul> <p><b>Respiration:</b></p> <ul style="list-style-type: none"> <li>• Difficulty in breathing</li> <li>• Asthma</li> <li>• Swollen, red, sore tongue</li> </ul>	<p><b>these serious side effects.</b></p>
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**Tell your radiologist, 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](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What IOMERON® contains

<b>Active ingredient (main ingredient)</b>	Iomeprol
<b>Other ingredients (inactive ingredients)</b>	Trometamol Hydrochloric acid Water

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

### Serious side effects

Serious side effects	What to do
<p><b>General:</b></p> <ul style="list-style-type: none"> <li>• Life threatening allergic reaction</li> <li>• Passing less urine than is normal</li> <li>• Protein in urine</li> <li>• Faecal incontinence</li> <li>• Paralysis</li> </ul> <p><b>Gastrointestinal tract:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</b></p>

## **What IOMERON® looks like**

IOMERON® is a sterile solution, which is supplied in vials with rubber stoppers. It is available in the following different strengths and sizes:

### **IOMERON® 300**

30.62 g/50 mL injection vial (AUST R 63955)

61.24 g/100 mL injection vial (AUST R 63957)

### **IOMERON® 350**

35.72 g/50 mL injection vial (AUST R 63960)

71.44 g/100 mL injection vial (AUST R 63961)

142.88 g/200 mL injection vial (AUST R 63963)

## **Who distributes IOMERON®**

### **Sponsor:**

Bracco Pty Ltd

14 Allambie Avenue, East Lindfield

NSW 2070

### **Australian distributor:**

Regional Healthcare Group

Medi-Consumables Pty Ltd

(ACN 001 394 323)

3-11 Primrose Avenue

ROSEBERY NSW 2018

### **New Zealand distributor:**

Regional Health Limited

PO Box 101-140

North Shore Mall Centre

Auckland

New Zealand

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