

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about Iomeron®.

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 Iomeron® 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 Iomeron® is used for

Iomeron® (iomeprol) is an iodine-containing dye, called a "contrast medium".

Iomeron® 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 the radiological visualisation of the vascular, renal and other physiological systems.

Injection of Iomeron® into the spinal cord allows the nerve within the spine to be seen in the X-ray. The resulting X-ray photographs may help your doctor to diagnose your illness or problem. This medicine belongs to a group of medicines called contrast agents.

Ask your radiologist or doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you are given Iomeron®**When you must not be given it**

You must not be given Iomeron® if you have an allergy to:

- any medicine containing iomeprol
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body;
- rash, itching or hives on the skin.

You must not be given Iomeron®:

- if 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)
- if you suffer from kidney disease or a combination of severe liver and kidney disease
- if you underwent a myelography procedure during the last 48 hours

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you have any questions not answered in this leaflet please ask the medical staff supervising your scan.

Before you are given it

Tell your radiologist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your radiologist or doctor if you have or have had any of the following medical conditions:

- asthma.
- allergy such as hay fever or food allergy
- an overactive thyroid gland or goitre (neck swelling of the thyroid gland).
- diabetes and being treated with metformin (Diabex, Diaformin or Glucophage). You must not take this medication for 48 hours before, and 48 hours after your X-ray to avoid harming your kidneys. Also, on making the appointment for the X-ray, remember to tell your radiologist that you are taking metformin but that you will not be taking it for at least 48 hours before, or 48 hours after the X-ray. Tell your radiologist again when you arrive for your X-ray appointment. If you are unsure about this or what to do, discuss it with your doctor.
- phaeochromocytoma (a tumour which raises blood pressure).
- 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, for example, stroke, bleeding inside the skull or brain, accumulation of fluid on the brain, multiple sclerosis, brain tumours or tumours (or cancer) spreading to the brain, epilepsy, transient ischaemic attacks (mild strokes).
- alcoholism (there is an increased risk of seizure (fit))
- addiction to, or dependence on drugs or medicines (there is an increased risk of seizure (fit)).
- inflammation of the female sex organs. This is only relevant if you are undergoing a uterine x-ray.
- myasthenia gravis
- sickle-cell disease

Tell your doctor if you are pregnant or intend to become pregnant.

It is not known if Iomeron® harms the developing baby. X-rays can be harmful to unborn babies. Iomeron® should therefore not be used in pregnancy unless there are compelling reasons. Your doctor and/or radiologist can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed.

It is not known if Iomeron® passes into human breast milk. 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.

If you have not told your doctor/radiologist about any of the above, tell him/her before you are given Iomeron®.

Taking other medicines

Tell your radiologist, doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Iomeron® may interfere with each other. These include:

- Neuroleptics - (medicines used for the treatment of some mental disorders - sometimes also called major tranquillisers). Check with your doctor or pharmacist if you are not sure whether you are taking a neuroleptic.
- Antidepressants - (medicines used for the treatment of depression). Check with your doctor or pharmacist if you are not sure whether you are taking an antidepressant.
- Anticonvulsants - Any medicine used for the treatment of epilepsy or fits. Check with your doctor or pharmacist if you are not sure whether you are taking an anticonvulsant.
- Certain medicines used to treat diabetes such as metformin. Check with your doctor or pharmacist if you are not sure whether you are taking metformin.
- Nephrotoxic drugs - medicines which can have a side effect of damaging the kidney in certain doses and under certain conditions. Check with your doctor or pharmacist if you are not sure whether you are taking a nephrotoxic drug.
- Corticosteroids (a class of steroid hormones) may promote and affect the signs and symptoms of arachnoiditis (inflammation of arachnoid). Check with your doctor or pharmacist if you are not sure whether you are taking a corticosteroid.

These medicines may interact or affect the way Iomeron® works. Your doctor may ask you not to take certain medicines for 48 hours before receiving an injection of IOMERON®.

Your radiologist, doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Iomeron® is given

Follow all directions given to you by your radiologist, doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor for help.

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.

How much to take:

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.

How to take it:

Iomeron® will be injected into a blood vessel or any other parts of the body by your radiologist/doctor.

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®.

What if you are given too much (overdose)?

The radiologist/doctor giving you Iomeron® will be experienced in its use, so it is unlikely that you will be given an overdose.

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.

Immediately telephone the Poison Information Centre on 13 11 26 in Australia or 0800 764 766 in New Zealand for any advice if you think you or anyone else may have taken too much Iomeron. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Iomeron®

Things you must do:

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

Things you must not do:

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.

Your radiologist will make appropriate records during your treatment and will note any unexpected effects you may experience.

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your radiologist or doctor to answer any questions you may have.

Tell your radiologist or doctor if you notice any of the following and they worry you:

- flushing
- heat sensation
- headache

- nausea
- disturbance of taste sensation
- pain at the site where Iomeron® is injected;

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor or radiologist as soon as possible if you notice any of the following:

- abdominal pain
- vomiting
- chest pain
- back pain
- chills
- fatigue
- fever
- headache
- swelling
- generally feeling unwell
- pain, bleeding and swelling at the site of injection
- changes in heart rate or heart beat (fast, slow or irregular)
- ECG change
- high or low blood pressure
- heart attack
- palpitation
- shock
- fainting
- confusion
- dizziness
- dry mouth
- mood swings
- paralysis
- muscle stiffness
- low muscle strength
- increased salivation
- nervousness
- numbness or weakness of arms and legs
- sensation of tingling, prickling or numbness of the skin
- drowsiness
- excessive hairiness
- itching
- rash
- skin discolouration
- sweating
- inflammation of the lip
- diarrhoea
- difficulty in swallowing
- burping
- swollen, red, sore tongue
- abnormal vision
- swollen runny eyes
- eye pain
- unusual weakness
- difficulty in breathing
- asthma
- coughing
- sore throat and discomfort when swallowing
- runny or blocked nose
- feeling of tension or fullness in the nose and behind the ears (sinusitis)
- swelling of the throat
- urinary incontinence

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor or radiologist if you notice any of the following and they worry you:

- life threatening allergic reaction
- heart failure
- collapse due to very low blood pressure
- CNS disturbances such as tremor, muscular spasms, loss of consciousness, loss of ability to comprehend language, loss of smell, taste, convulsive seizures and coma
- Passing less urine than is normal
- Protein in urine
- Faecal incontinence

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your radiologist, doctor or pharmacist if you notice anything that is making you feel unwell.

Some people may experience other side effects after an injection of Iomeron®. Some of these side effects can only be found when your radiologist or doctor does tests from time to time to check your progress.

Your radiologist/doctor may give you other medicines before you receive an injection of Iomeron® to prevent these side effects from occurring.

STORAGE of Iomeron®

Storage

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.

Product description

What it 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:

Ingredients

Iomeron® 300

Each mL of Iomeron® 300 contains: 612.4 mg iomeprol.

It also contains:

- 1 mg trometamol
- 0.24 hydrochloric acid
- water for injections to make 1 mL.

Iomeron® 350

Each mL of Iomeron® 350 contains: 714.4 mg iomeprol

- 1 mg trometamol
- 0.24 drochloric acid
- water for injections to make 1 mL.

Distributor/Supplier

Sponsor:

Bracco Pty Ltd
C/- Ernst & Young
Level 15
321 Kent Street
Sydney NSW 2000

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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Iomeron® 300 is available in the following pack sizes:

20 mL vial - AUST R 91369
50 mL vial - AUST R 63955
75 mL vial - AUST R 63956
100 mL vial - AUST R 63957
150 mL vial - AUST R 63958
200 mL vial - AUST R 63959

Iomeron® 350 is available in the following pack sizes:

20 mL vial - AUST R 91370
50 mL vial - AUST R 63960
75mL vial - AUST R 68109
100 mL vial - AUST R 63961
200 mL vial - AUST R 63963
250 mL vial - AUST R 63964