PACKAGE LEAFLET: INFORMATION FOR THE USER

Iomeron® 350 solution for injection, multi-dose container

(Iomeprol)

The name of your medicine is Iomeron 350 solution for injection, which will be called Iomeron throughout this leaflet.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Iomeron is and what it is used for

Iomeron is a special dye (or contrast agent) which blocks X-rays because it contains iodine. Iomeron works by helping your doctor to see the internal body structures on an X-ray picture. Your doctor has prescribed Iomeron to help view different parts of your body during a CT-scan. This medicine is for diagnostic use only.

2. What you need to know before you are given Iomeron

You should not be given Iomeron if you:
- Are allergic to Iomeprol, or to any other ingredients of Iomeron (see list of ingredients in Section 6).

Warnings and precautions

Talk to your doctor or pharmacist before being given Iomeron if you have any of the following conditions:
- A history of allergy or asthma;
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after receiving iodinated contrast media;
- Diabetes;
- Problems when you urinate;
- Sickle cell disease (your body produces abnormally shaped red blood cells, which leads to anaemia);
- Heart problems;
- Pulmonary hypertension;
- Kidney or liver problems;
- Over-active or enlarged thyroid gland;
- Myasthenia gravis (a disease causing weak muscles);
- Stroke, mini-stroke, brain tumor or other brain diseases;
- A history of epilepsy;
- Alcoholism;
- Drug addiction;
- Phaeochromocytoma (a tumor of the adrenal gland);
- Multiple myeloma (a tumor of white blood cells);
- Paraproteinaemia (abnormal proteins in the blood).

Particular care should be taken in children under 1 year of age and in the elderly. These groups might be susceptible to adverse reactions.

Tell your doctor if you have had thyroid function tests performed in the past.

During, or shortly after the imaging examination you may experience a short-term brain disorder called encephalopathy. Tell your doctor immediately if you notice any of the symptoms related to this condition, as described in section 4.

Thyroid disorders may be observed following administration of Iomeron in both children and adults. Infants may also be exposed through the mother during pregnancy. Your doctor may need to perform throid function tests before and/or after the administration of Iomeron.

Take special care with Iomeron:

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with the use of Iomeron. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Iomeron

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. Especially tell your doctor if you are taking the following medicines, as they may react with Iomeron:
- painkillers
- antiemetics (treatments that prevent vomiting)
- metformin (a treatment for diabetes)
- anti-epileptics (treatment for epileptic fits)
- drugs for psychiatric illness.

Especially tell your doctor if you are taking the following medicines, as they might increase the possibility that you will suffer from side effects:
- beta blockers (a treatment for heartbeat problems)
- antidepressant
- interleukin-2 (a treatment for cancer).

It may still be all right for you to be given Iomeron and your doctor will be able to decide what is suitable for you.

Iomeron with food and drink

You should maintain a normal diet until 2 hours before your X-ray examination and then avoid eating until after the examination is complete.

Pregnancy and breast-feeding

If you are pregnant, you should only be given Iomeron if your doctor believes it is clearly necessary. Tell your doctor if you are or believe you might be pregnant.
If you are pregnant, and have received Iomeron during pregnancy, it is recommended to monitor the thyroid function of your baby after birth.
Stopping breastfeeding is not necessary.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There is no known effect of Iomeron on the ability to drive or operate machines.

3. How you are given Iomeron

Iomeron will be given to you by a doctor or a nurse in hospital or clinic. It will be injected into a vein.

Dosage

The recommended dose depends on which part of the body is being X-rayed and is usually in the range 2-250 ml. Your doctor may decide to vary this dose or to repeat the dose if required.
The dose for children depends also on the age and the body size.
You will be kept under observation for at least 30 minutes after the examination.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you are given more Iomeron than you should:

You should know that the hospital area or clinic where Iomeron is given to you is well equipped to treat any effects of overdose.

4. Possible side effects

Like all medicines, Iomeron can cause side effects, although not everybody gets them. They are usually mild to moderate and not prolonged. However, severe and life-threatening reactions sometimes leading to death have been reported. After administration by injection into a vein or artery, most reactions occur within minutes, and after injection into body cavities or spine, most reactions occur within a few hours or longer.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Common (in more than 1 in 100 patients, but less than 1 in 10 patients):
- sensations of warmth.

Uncommon (in more than 1 in 1,000, but less than 1 in 100 patients):
- headache;
- dizziness;
- increased blood pressure;
- shortness of breath;
- nausea, vomiting;
- flushing, nettle rash, itching;
- chest pain, warmth and pain at the injection site.

Rare (in more than 1 in 10,000, but less than 1 in 1,000 patients):
- fainting;
- slow or rapid heartbeat;
- decreased blood pressure;
- rash;
- back pain;
- asthenia, stiffness, fever;
- changes in some blood analysis.

Not known (cannot be estimated from the available data):
- contact a doctor immediately if you experience serious skin reactions such as:
  - blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)
  - a red, scaly rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
  - widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)
- reduction in blood platelets, which increases risk of bleeding or bruising;
- haemolytic anaemia (abnormal breakdown of red blood cells, which may cause fatigue, rapid heart rate and shortness of breath);
- serious allergic reaction which causes difficulties in breathing or dizziness;
- hyperthyroidism;
- anxiety, confusion;
- coma, temporary problems in blood supply to the brain, with few or no residual after-effects (TIA), paralysis, syncope, fits, loss of consciousness, difficulties in speaking, abnormal sensations (tingling, itching), memory loss, drowsiness, taste disorders;
- brain disease (encephalopathy) with symptoms including headache, vision problems, loss of vision, confusion, seizures, loss of coordination, loss of movement on one side of the body, problems with speech and loss of consciousness;
- temporary blindness, impaired eyesight, eye irritation, eye watering, light sensitivity;
- cardiac arrest, myocardial infarction, heart failure, chest pain, irregular heartbeat, heart conduction disturbances, heart rhythm disorders;
- blood circulation failure (circulatory collapse) or shock (sharp drop in blood pressure, pallor, restlessness, weak rapid pulse, clammy skin, reduced consciousness) caused by sudden and severe dilation of the blood vessels, hot flushes, redness, pallor, blue discolouration of the skin and mucous membranes, blood clot, vasospasm and consequent ischemia;
- respiratory arrest, acute shortness of breath (acute respiratory distress syndrome), fluid on the lungs, swelling of the throat, sudden constriction of the airways (bronchospasm), asthma, cough, throat discomfort, inflammation of the nasal lining, characterised by blocked nose, sneezing and discharge (rhinitis), hoarseness (dysphonia);
- diarrhoea, abdominal pain, excessive saliva flow, difficulties in swallowing, enlarged salivary glands;
- serious allergic reaction which causes swelling of the face or throat, increased sweat production;
- joint pain;
- acute kidney failure;
- reaction at the site of injection including pain and swelling, localised feelings of coldness;
- generally feeling ill (malaise), thirst;
- development of circular skin blisters (the centre of which is often paler in colour) (erythema multiforme);
- abnormal electrocardiogram heart tracing.

Transient hypothyroidism may occur in children younger than 3 years of age.
Iomeron safety profile is similar for children and adults.

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

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Iomeron
You will not be required to store the medicine yourself. Your doctor or hospital pharmacist will know how to store Iomeron.
Keep this medicine out of the sight and reach of children, stored below 30 °C and protected from light.
The maximum use time after a bottle stopper has been pierced is 10 hours.
Do not use this medicine after the expiry date stated on the label. The expiry date refers to the last day of that month.
Do not throw away any medicine via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information
What Iomeron contains
One ml of Iomeron 350 contains 71.44% of the active substance Iomeprol corresponding to 350 mg iodine.
The other ingredients are trometamol, hydrochloric acid and water.

What Iomeron looks like and contents of the pack
Iomeron is supplied in glass bottles containing 500 ml of solution (boxes of 1, 5 and 6).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Bracco UK Ltd, Magdalen Centre, The Oxford Science Park, Oxford, OX4 4GA, United Kingdom

Manufacturers
Patheon Italia S.p.A., 2° Trav. SX Via Morolense 5, 03013 Ferentino (FR), Italy
Bracco Imaging S.p.A., Bioindustry Park, Via Ribes 5, 10010 Colleretto Giacosa (TO), Italy
BIPSO GmbH, Robert-Gerwig-Strasse 4, 78224 Singen, Germany

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The following information is intended for healthcare professionals only:

Before use, examine the product to assure that the container and closure have not been damaged. Do not use the solution if it is discolored or particulate matter is present.
The stopper should be pierced only once. The use of proper withdrawal cannulas for piercing the stopper and drawing up the contrast medium is recommended.
Multi-dose containers should be used only in conjunction with an automatic injector which has been approved for multipatient use.
After each patient, the connector between the injector and the patient should be replaced. All other devices should be replaced following the injector manufacturer's instructions. In any case, strictly follow the manufacturer's instructions.
Any unused product or waste material should be disposed of in accordance with local requirements.

<u>Posology and method of administration</u>

computed tomography		
brain	adults children	50 - 150 ml *
body	adults children	40 - 150 ml max 250 ml *

* According to body size and age