PACKAGE LEAFLET: INFORMATION FOR THE USER

Iomeron 150 mgI/ml solution for injection
iomeprol 30.62% w/v
(150 mg Iodine per ml)

The name of your medicine is Iomeron 150 mgI/ml solution for injection, which will be called Iomeron throughout this leaflet.

Read all of this leaflet carefully before you start taking 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, nurse or pharmacist.
- This medicine has been prescribed for you only. 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, nurse 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 the blood vessels, or urinary tract or bladder using X-rays.

This medicine is for diagnostic use only.

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

You must 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, nurse 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
- paraproteinaemia (abnormal proteins in the blood)
- diabetes
- problems when you urinate
- sickle cell disease (your body produces abnormally shaped red blood cells, which leads to aneamia)
- multiple myeloma (a tumor of white blood cells)
- heart problems, including coronary heart disease

- kidney problems (because your doctor might wish to review your treatment or any planned intervention)
- 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
- a growth of the adrenal gland

Tell your doctor if you are to have a thyroid function test, as iomeprol may interfere with these tests.

During or shortly after the imaging procedure you may experience a short-term brain disorder called encephalopathy. Tell your doctor straight away if you notice any of the symptoms related to this condition 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 thyroid 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.

In all patients dehydration should be avoided and it might be necessary to give fluids to ensure this. Particular care should be taken in children and in the elderly, and in patients with underlying conditions such as liver, cardiac or renal disorders, diabetes, and those who are particularly susceptible to dehydration.

Other medicines and Iomeron
Tell your doctor, nurse or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. 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)
- drug for psychiatric illness
- vasopressor agents (used to increase blood pressure)

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)
- interferon (a treatment for cancer)
- 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

Unless otherwise instructed by the doctor, you should maintain a normal diet on the day of the examination.

Pregnancy, breast-feeding, and fertility
If you are pregnant or breast-feeding, you should only be given Iomeron if your doctor believes it is clearly necessary. Tell your doctor if you are pregnant or breast-feeding or believe you might be pregnant or you are planning to have a baby. If you are pregnant, and have received Iomeron during pregnancy, it is recommended to monitor the thyroid funtion of your baby after birth.

Stopping breastfeeding is not necessary.

Ask your doctor, nurse 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 an artery or a vein.

Dosage
The recommended dose depends on which part of the body is being X-rayed and is usually in the range 0.2 ml - 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, nurse 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 (between 1 in 10 and 1 in 100 patients)
- feeling hot

Uncommon PIL (between 1 in 100 and 1 in 1000 patients)
- headache
- dizziness

- increase in blood pressure
- breathlessness
- vomiting
- feeling sick (nausea)
- redness
- swelling of the skin
- itching
- chest pain
- warmth and pain at the injection site

Rare (between 1 in 1000 and 1 in 10000 patients)

- slow or fast heartbeat, irregular heartbeat
- decrease in blood pressure
- rash
- back pain
- severe weakness
- fever
- changes in results of some laboratory tests which might be carried out by a doctor, including kidney, cardiac, U&E and blood tests.

Not known: (cannot be estimated)

- 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)
- unexplained bruising or bleeding (due to low platelet levels)
- haemolytic anaemia (abnormal breakdown of red blood cells, which may cause fatigue, rapid heart rate and shortness of breath)
- severe allergic reaction
- hyperthyroidism
- anxiety, confusion
- coma, mini-stroke, limited or no blood flow to the brain, paralysis, fits, loss of consciousness or fainting
- brain disorder (encephalopathy) with symptoms including headache, difficulties with vision, loss of vision, confusion, seizures, loss of coordination, loss of movement in one side of the body, problems with speech, and loss of consciousness
- difficulty speaking
- abnormal skin sensations (as tingling or tickling)
- disturbance of memory
- strong desire for sleep
- changes in taste
- visual problems, including transient blindness
- eye irritation, increased tears
- cardiac arrest, heart attack, heart failure, abnormal heart rhythm
- shock, flushing due to enlargement of blood vessels, pale skin (pallor), blue discoloration of skin and mucous membranes, blood clot, vasospasm and consequent ischemia

- breathing stopped, difficulty in breathing, water in the lungs, swollen voice box, asthma, cough runny nose, throat discomfort, blocked nose
- diarrhea, abdominal pain, increased salivation, enlarged salivary gland, difficulty in swallowing
- swelling of the skin, increased sweating
- joint pain
- acute kidney failure
- swelling at the injection site
- feeling cold
- feeling of discomfort or unease
- thirst
- pelvic pain

Transient hypothyroidism may occur in children younger than 3 years of age.

Reporting of side effects
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 HPRA Pharmacovigilance - Earlsfort Terrace - IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 - Website: www.hpra.ie - e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

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

5. How to store Iomeron

You will not be required to store the medicine yourself. Your doctor, nurse or hospital pharmacist will know how to store Iomeron.
Keep this medicine out of sight and the reach of children. Store below 30 °C. Keep in the original container.
Do not use this medicine after the expiry date stated on the label. The expiry date refers to the last day of that month.
Iomeron should be given to you immediately once drawn up into the syringe.

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 150 contains 30.62% of the active substance iomeprol corresponding to 150 mg iodine.
The other ingredients are trometamol, hydrochloric acid and water for injection.

What Iomeron looks like and contents of the pack
Iomeron is supplied in glass bottles containing: 50, 75, 100, 150, 200 or 250 ml of clear, colourless solution.
Not all packs sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Bracco Imaging spa, Via Egidio Folli 50, 20134 Milano, Italy

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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