Proposed Patient Information Leaflet for IMERON

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

IMERON 200 solution for injection

IMERON 250 solution for injection

IMERON 300 solution for injection

IMERON 350 solution for injection

IMERON 400 solution for injection

Iomeprol

Read all of this leaflet carefully before you are given IMERON injection

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What IMERON is and what it is used for
2. What you need to know before IMERON is administered
3. How IMERON is administered
4. Possible side effects
5. How to store IMERON
6. Contents of the pack and other information

1. What IMERON is and what it is used for

IMERON is an injectable contrast medium which contains iodine. Under certain circumstances,

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your doctor will want to investigate a certain area of your body with an x-ray scan. IMERON injection acts like a dye to show the relevant area of your body more clearly on the x-ray film. This medicine is for diagnostic use only.

2. What you need to know before IMERON is administered to you

IMERON should not be administered to you:

- If you are hypersensitive (allergic) to iomeprol or any of the other ingredients of IMERON (listed in section 6).
- If you suffer from a disease called Waldenström's paraproteinaemia (an increase in the cells which produce antibodies).
- If you have cancer called multiple myeloma (cancer of plasma cells in bone marrow).
- If your liver and kidney functions are severely impaired.
- If you are pregnant or suspect you are pregnant.
- IMERON 200: If you have inflammation of the pelvic cavity (symptoms include stomach pain and tenderness, fever and irregular menstrual periods).
- IMERON 200/250/300 should not be administered to you together with corticosteroid medicine.

Warnings and precautions:

IMERON is only administered in hospitals or clinics.

Tell your doctor or health care provider before being given the injection:

- If you have any known hypersensitivities or if you have ever developed a previous allergic reaction after using contrast media, especially iodine-containing contrast media.
- If you have asthma.
- If you are elderly.
- An overactive thyroid gland (hyperthyroidism) or a swollen neck due to an enlarged thyroid gland (goitre).
- If you have kidney problems or if you are being treated with metformin for your condition

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namely diabetes mellitus (high blood sugar) (see section 2 “Other medicines”), you are at higher risk for developing more kidney problems.

- Heart or blood circulation problems, because in the rare event that you have an allergic reaction, it is more likely to be serious or fatal.
- If you suffer from epilepsy, have a history of seizures, or any other condition affecting the brain.
- If you are taking medicines to treat pain, depression, nausea or vomiting. Your doctor may ask you to stop the medication for a short period.

Special care should be taken with IMERON:

- If you develop any allergic reaction after the procedure. Symptoms that can indicate an allergic reaction include nausea, vomiting, itchy or redness of skin and shortness of breath (see section 4 “Possible side effects”).
- If you are using beta-adrenergic blocking medicines (e.g. propranolol or bisoprolol) for your asthma and you develop signs of bronchospasma (see section 4 “Possible side effects”).
- You should drink plenty of fluid and hydrate properly, before and after the procedure.
- If you develop symptoms of a thyroid storm (see section 4 “Possible side effects”) due to your thyroid problems.
- If you have diabetes mellitus or reduced kidney function special care should be taken to maintain proper hydration in order to reduce risk of damage caused to kidneys or possible complications such as lactic acidosis (see section 4 “Possible side effects”).
- If you have phaeochromocytoma (a hormone-secreting tumour that can occur at the top of the kidneys in the adrenal glands). You should be premedicated with an alpha-receptor blocker (e.g. doxazosin or tamsulosin) to prevent hypertensive crises (elevated blood pressure).
- If you are in a current state of anxiety or suffering from pain, your side effects or reaction to the medicine may be increased, therefore your doctor should look at treating you with a sedative or tranquilliser.
- If you suffer from cerebrovascular disease (conditions where the blood flow in your brain is

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affected).

- If you develop encephalopathy (damage or disease affecting the brain)(see section 4 “Possible side effects”).
- If you suffer from alcoholism or drug addiction problems.
- If you have myasthenia gravis (a neuromuscular disorder causing weakness of muscles that can lead to paralysis).
- If you suffer from any vascular or circulatory disorders, including blood clots or arterial obstructions, inflammation of your veins, local infections or narrowing of your blood vessels limiting blood an oxygen supply to your organs.

Children and adolescents:

New-born patients are particularly more prone to develop electrolyte imbalances and haemodynamic alterations (wherein your circulatory system is affected by blood flow mechanisms). Hypothyroidism has also been observed in children after exposure to contrast mediums.

Other medicines and IMERON:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if any of the following applies to you:

- There is a risk if you have reduced kidney function and when you are taking diabetes medicines (e.g. metformin). Discontinue treatment before examination with IMERON, up to 48 hours after the exam. After having undergone blood tests, your doctor will tell you when you can resume your treatment.
- If you are taking beta-blockers to treat heart or blood pressure. They can make allergic reactions worse.
- If you are taking corticosteroids (anti-inflammatory medicines), analgesics (pain killers),

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antidepressants, anti-emetics (medicine to help with nausea and vomiting) or neuroleptics. Discontinue treatment 48 hours before examination with IMERON. Your doctor will tell you when you can resume your treatment.

IMERON may interfere with laboratory tests results, including tests for bilirubin, proteins or inorganic substances, such as copper, iron, calcium and phosphate.

IMERON 200/250/300 should not be administered to you together with epidural or intrathecal corticosteroid medicine as this may promote the signs and symptoms associated with inflammation of the arachnoid (arachnoiditis).

IMERON with food or drink:

Unless your doctor has instructed you otherwise, you may eat on the day of the examination. However, you should refrain from eating two hours before the procedure.

If you have a disorder of your body water and body salts balance this will be corrected before the examination. Do not reduce the amount you normally drink before the investigation, especially if you have any of the following conditions:

- Diabetes mellitus,
- gout,
- polyuria (production of large amounts of urine which is pale in colour),
- oliguria (production of small amounts of urine).

Also, do not reduce the fluid intake of babies, young children, or in someone who is in a very poor general state of health.

IMERON with alcohol:

Tell your doctor if you usually drink a lot of alcohol before being examined with IMERON, as this may increase the risk of developing central nervous system disorders (such as epilepsy or seizures).

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Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before IMERON is administered.

You should not be given IMERON if you are pregnant (see section 2 “IMERON should not be administered”).

If you are breastfeeding your baby, you may have to stop nursing prior to the administration of IMERON and should not start until 24 hours after the administration of this medicine.

Driving and using machines:

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

However, you should not drive or operate machinery for 24 hours after the examination as you may have a delayed reaction to IMERON.

3. How IMERON will be administered

You will not be expected to give yourself IMERON. It will be given to you by a person who is qualified to do so.

IMERON will be injected into a vein, into an artery, or into a body cavity.

Your doctor will decide how much IMERON is needed for your particular investigation. He/she will explain how everything works and what position you should lie in on the x-ray table.

The dose of IMERON varies depending on the investigation, your weight and your age.

You will be asked to stay in the hospital for 1 hour after your examination. If you develop any symptoms during this time, you should tell your doctor immediately.

If you receive more IMERON than you should:

Your doctor or other health care provider will administer IMERON and will control the dosage. In

the event of overdosage, your doctor will manage the overdosage.

4. Possible side effects

IMERON can have side effects.

Not all side effects reported for IMERON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving IMERON, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving IMERON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat,
  which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to IMERON. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Flushing, feeling hot, increased sweating.
- Dizziness and feeling faint**,** unconsciousness, coma and fit (convulsion).
- Inability to move some parts or all of your body.
- Difficulty breathing, feeling of suffocation.
- Itchy or watery eyes, tickling in the throat or nose, hoarseness, coughing or sneezing.
- Pain or tightness in the chest.
- Changes to your heartbeat (such as beating slower or faster than normal or skipping beats).

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- Heart attack (chest pain, pain radiating into your arm, sweating, difficulty breathing, tightness in your chess, heartburn).
- Kidneys not working properly, production of small amounts of urine, or protein in your urine.
- Unexplained bleeding, nosebleeds, bruising or pinpoint bleeds on your skin.
- Blindness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with a common frequency:

- Headache.
- Pale skin.
- Nausea (feeling sick).
- A sensation of pain and warmth at the injection site.

Side effects with an uncommon frequency:

- Agitation (state of anxiety or nervous excitement).
- Dizziness.
- Feeling weak.
- Changes to and blood pressure.
- Stuffy nose, difficult breathing.
- Vomiting (being sick).
- Redness of skin.
- Sweating.
- Back pain.
- Bleeding at the injection site.

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*Side effects with a rare frequency***:**

- Shakiness and confusion.
- Problems with your eyesight and speech.
- Blue lips; blue or pale skin.
- Widening of blood vessels; decreased blood flow to parts of the brain.
- Muscle spasm; weakness or loss of strength.

Side effects occurring with an unknown frequency:

- Haemolytic anaemia (abnormal breakdown of red blood cells, which may cause fatigue, rapid heart rate and shortness of breath).
- Anxiety.
- Abdominal pain and diarrhoea.
- Loss of memories (amnesia).
- Taste disturbances.
- Sleeplessness.
- Eye discomfort in bright light, increased tearing, inflammation of your eyes (redness, itching or pain).
- Asthma, high pitched sound while breathing.
- Runny nose.
- Sneezing or throat discomfort.
- Changes in your voice.
- Pancreatitis (inflammation of your pancreas causing pain of your stomach area radiating to your back, nausea, vomiting, increased heartbeat, fever).
- Difficulty swallowing, increased saliva, enlarged salivary glands.
- Joint pain or muscle weakness.
- Chills, fever.
- Tiredness.

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- Increased thirst.
- Changes in blood test results.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of IMERON.

5. How to store IMERON

- Store at or below 25 ºC.
- Protect from light and X-rays.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the medicine after the expiry date printed on the carton and bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IMERON contains:

The active ingredient is iomeprol.

IMERON 250: 1 mL contains 510 mg iomeprol in aqueous solution equivalent to 250 mg iodine.

IMERON 300: 1 mL contains 612 mg iomeprol in aqueous solution equivalent to 300 mg iodine.

IMERON 350: 1 mL contains 714 mg iomeprol in aqueous solution equivalent to 350 mg iodine.

IMERON 400: 1 mL contains 816 mg iomeprol in aqueous solution equivalent to 400 mg iodine.

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The other ingredients are trometamol, hydrochloric acid, water for injection.

What IMERON looks like and contents of the pack:

Clear solution, practically free from visible particles in suspension.

Clear colourless glass containers (vials/bottles) with closures made of elastomeric material (chlorobutyl rubber or bromobutyl rubber) and flip-off caps composed of an aluminium ring with a central hole through which a polypropylene disc is inserted which may be available in different colours.

Pack size:

IMERON 200: 75 mL and 150 mL bottles.

IMERON 250: 50 mL and 150 mL bottles.

IMERON 300: 20 mL, 50 mL, 75 mL, 100 mL, 150 mL and 200 mL bottles.

IMERON 350: 50 mL, 100 mL, 150 mL and 200 mL and 500 mL bottles.

IMERON 400: 50 mL, 100 mL, 200 mL and 500 mL bottles.

Holder of certificate of registration and manufacturer:

Axim Pharmaceuticals (Pty) Ltd

63 Old Pretoria Main Road

Halfway House 1685

Midrand, South Africa

Tel: +27 11 314 0140

This leaflet was last revised:

To be allocated.

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Registration numbers:

IMERON 200: 32/28/0714

IMERON 250: 32/28/0715

IMERON 300: 32/28/0716

IMERON 350: 32/28/0717

IMERON 400: 32/28/0718

Date of registration:

3 April 2000

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