Patient Information Leaflet for JOPAMIRON

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

JOPAMIRON 300 (50 mL) solution for injection

JOPAMIRON 300 (100 mL) solution for injection

JOPAMIRON 300 (200 mL) solution for injection

JOPAMIRON 370 (50 mL) solution for injection

JOPAMIRON 370 (100 mL) solution for injection

JOPAMIRON 370 (200 mL) solution for injection

JOPAMIRON 370 (500 mL) solution for injection

Iopamidol

Sugar free

Read all of this leaflet carefully before you are given JOPAMIRON.

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

1. What JOPAMIRON is and what it is used for

JOPAMIRON contains the active substance iopamidol.

JOPAMIRON is a contrast medium which is injected for use in diagnostic purposes during a radiological examination. JOPAMIRON works by helping your health care provider to see the internal body structures on an X-ray picture. Different radiographic (X-ray) procedures can be performed and depending on the procedure, certain areas in your body or any undergoing pathological processes can be seen more clearly.

2. What you need to know before you receive JOPAMIRON

JOPAMIRON should not be administered to you:

- If you are hypersensitive (allergic) to iopamidol, iodine or any of the other ingredients of JOPAMIRON (listed in section 6).
- If you are being treated with medicines such as corticosteroids (a type of anti-inflammatory medicine) by intrathecal administration (an injection into the space surrounding spinal cord) and the radiological examination requires the administration of JOPAMIRON in the intrathecal space (see section 2 “Other medicines and JOPAMIRON”).
- If you have to repeat, in a short time, the radiological examination with JOPAMIRON in the intrathecal space (space surrounding spinal cord), since the repeated administration of JOPAMIRON could cause undesirable effects due to excessive dosage.
- If you have cerebral fits e.g. fits or seizures (a sudden, uncontrolled electrical disturbance in the brain).
- If you are suffering from a condition known as hyperthyroidism (overactivity of the thyroid gland).
- If you have Waldenströms macroglobulinemia (a rare type of cancer that begins in the white blood cells).
- If you have multiple myeloma (a cancer that forms in a type of white blood cell called a plasma cell).
- If you have severe kidney disease.

- If you are pregnant (see section 2 “Pregnancy and breastfeeding).

Warnings and precautions

JOPAMIRON is for diagnostic use only.

JOPAMIRON is only administered in hospitals or clinics.

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

- If you have any known hypersensitivities or if you have ever developed a previous allergic reaction after using contrast medicines.
- If you are a known epileptic or have a history of epilepsy (having fits/seizures). It is important that your epilepsy be properly managed or in some cases, your doctor can even increase your anticonvulsant therapy before the examination.
- If you have a history of bronchial asthma (a lung disease causing difficulty in breathing), especially if you have been taking beta-blocking medicines (e.g. propranolol or carvedilol).
- If you have congestive heart failure (a condition in which the heart cannot pump enough blood to meet the body's requirement). You should be carefully observed for several hours following the procedure.
- If you have any underlying conditions or disease affecting the functioning of your liver or kidneys.
- If you have kidney problems or if you are being treated with certain diabetes medicines (e.g. metformin) or medicines that are toxic to the kidneys (see section 2 “Other medicines”), you are at higher risk for developing more kidney problems.
- If you have thyroid problems or develop symptoms of a thyroid storm [e.g. a rapid heartbeat, an increased temperature, diarrhoea and feeling sick, yellowing of the eyes and skin (jaundice), severe agitation, being confused, loss of consciousness].
- If you have previously been treated for Grave’s disease [an immune system disorder that results in the overproduction of thyroid hormones (hyperthyroidism)], it is also possible that symptoms of an overactive thyroid can reoccur.

- If you have sickle cell disease (your body produces abnormally shaped red blood cells, which leads to anaemia), it is important that you are properly hydrated with fluids and a high concentration of electrolytes.

Special care should be taken with JOPAMIRON:

- If you develop any allergic reaction after the procedure. Symptoms that can indicate an allergic reaction include nausea, vomiting, itchy or redness of skin, shortness of breath. Minor symptoms even include violent yawning, sneezing, tickling in the throat, hoarseness or coughing fits (see section 4 “Possible side effects”).
- If you suffer from cerebrovascular disease (conditions where the blood flow in your brain is affected) or have increased calcium levels in your blood.
- If you suffer from high blood pressure or have other risk factors such as arteriosclerosis (a build-up of plaque in the inner lining of an artery).
- If you have myasthenia gravis (a neuromuscular disorder causing weakness of muscles that can lead to paralysis).
- 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 α-receptor blockers (e.g. doxazosin or tamsulosin) to prevent hypertensive crises (elevated blood pressure).
- If you develop encephalopathy (damage or disease affecting the brain) (see section 4 “Possible side effects”).
- If an angiographic procedure is to be performed (an angiogram is a scan that shows blood flow through arteries or veins, or through the heart), caution is advised if you have severe diseases of the heart and blood vessels, including heart failure, severe inflammation of blood vessels (obliterative thromboangiitis).
- Severe systemic disease, embolism.
- If you suffer from pulmonary hypertension (a high blood pressure that affects arteries in the lungs and in the heart).
- If you suffer from a disorder known as homocystinuria (an inherited disorder in which the

body is unable to process certain building blocks of proteins properly).

- If a venographic procedure is to be performed (an x-ray exam that is performed to examine the health of the veins, typically in your legs), special caution should be exercised in patients with suspected phlebitis (a blood clot that causes pain and inflammation in veins located just under the skin), serious ischaemia (a restriction in blood supply to any tissues, muscles, or organs), local infections or a complete venous occlusion (narrowed, blocked or clotted vein).
- If you have previously had head injuries or you have a condition in which the pressure in your skull has increased, or if there is a possibility of suffering from a brain tumour.
- If you have recently had a stroke or a transient ischemic attack (TIA) (a mini stroke).
- If you have an abscess or suffer from blood loss due to badly bruising.
- If you have a history of convulsions, you should continue specific therapy.
- If you suffer from alcoholism or drug addiction problems.
- You should drink plenty of fluid and hydrate properly, before and after the procedure.
- If you are elderly.

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 JOPAMIRON

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

- 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 JOPAMIRON, 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 diuretics (e.g. hydrochlorothiazide or furosemide), ACE-inhibitors (e.g. enalapril) and/or beta-blocking medicines (e.g. propranolol or carvedilol) for your heart or blood pressure. You are at higher risk for developing adverse reactions.
- If you are taking other vasodilators such as papaverine (used to treat impotence).
- If you have recently given cholecystographic contrast media for diagnostic use to evaluate the conditions of your gall bladder.
- If you are taking medicines to treat psychiatric disorders (psychotropic medicines e.g. risperidone or haloperidol), painkillers, vomiting, allergies and anxiety, this may make you more liable to have seizures when being administered contrast mediums.
- If not specified by the doctor, treatment must be discontinued 48 h before the radiological investigation and can be resumed not earlier than 24 h afterwards medicines that modify the immune system's response, such as interleukin-2 and interferon, because adverse reactions may occur, such as erythema, fever or flu symptoms.

If you need to perform a thyroid test or laboratory tests for bilirubin, proteins or inorganic substances (e.g. iron, copper, calcium, phosphate) in the two weeks following the administration of the contrast medicine, talk to your doctor, as they may be altered.

JOPAMIRON with food and alcohol

Patients, especially newborns and children should be well hydrated prior to and following administration.

Tell your doctor if you usually drink a lot of alcohol before being examined with JOPAMIRON.

Pregnancy and breastfeeding

If you are pregnant, 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 you receive JOPAMIRON.

If you are planning to become pregnant, it is recommended to conduct X-ray examination during the

pre-ovulation phase of the menstrual cycle.

JOPAMIRON should not be used if you are pregnant (see section 2 “JOPAMIRON should not be administered”).

JOPAMIRON is excreted into the breast milk in low amounts.

Driving and using machines

It is not always possible to predict to what extent JOPAMIRON may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which JOPAMIRON affects you.

3. How JOPAMIRON will be administered

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

JOPAMIRON will be injected into a vein, into an artery, into the intrathecal space, e.g. the space surrounding the spinal cord or into a body cavity.

Your dosage will depend on the technique used and the desired type of examination.

Your doctor will tell you how long your treatment with JOPAMIRON will last. If you have the impression that the effect of JOPAMIRON is too strong or too weak, tell your doctor or pharmacist.

If you receive more JOPAMIRON than you should

Since a health care provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

4. Possible side effects

JOPAMIRON can have side effects.

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

If any of the following happens, stop receiving JOPAMIRON 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 JOPAMIRON. 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:

- Chest pain or changes in your blood pressure such as bradycardia (slow heart rate) or tachycardia (rapid or irregular heart rate).
- Kidney failure.
- Cardiac dysrhythmias (irregular heartbeat) or fibrillations (irregular heart rhythm).
- Bronchospasm (where your airways go into spasm making it difficult to breathe, which may cause wheezing or coughing).
- Reddish non-elevated, target-like or circular patches on the trunk, often with central 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 widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised

exanthematous pustulosis).

- Myocardial ischaemia or infarction (when the blood flow through the major arteries that supply blood to your heart slows or stops).
- Kounis syndrome (heart attack caused by an allergic reaction).
- Circulatory collapse (a life-threatening condition in which your heart suddenly can't pump enough blood to meet your body's needs) or shock.
- Respiratory arrest, respiratory failure, acute respiratory distress syndrome, respiratory distress (inability of your lungs or breathing system to function).
- Severe bacterial infection or inflammation of the meninges.
- Hemiplegia (muscle weakness, partial paralysis or inability to move one side of the body).
- 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.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Feeling hot.
- Nausea.

Less frequent side effects:

- Dizziness.
- Confusion.
- Differences in your taste sensations.
- Tingling or prickling, “pins-and-needles”.
- Changes in your blood pressure.
- Flushing or redness of the skin.
- Increased sweating.

- Muscle spasms.
- Back pain, neck pain or pain in your limbs such as arms or legs.
- Sensation of heaviness.
- Asthma.
- Changes in bodily temperature where you have fever, or if experience feeling differently, either feeling cold.
- Pain at site of injection.
- Chest pain.
- Vomiting.

Unknown side effects:

- Infection or inflammation of the inner eyelid (e.g. pink eye's).
- Sight disturbances, vision loss.
- Sensitivity for light exposure.
- Fits or seizures.
- Disorientation or restlessness.
- Feeling agitated.
- Dyspnoea (sensation of uncomfortable breathing).
- Feeling ill.
- Chills (rigors or trembling).
- Increased amount of saliva in the mouth or drooling.
- Muscle pain or weakness.
- Lowered level of consciousness.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of JOPAMIRON.

5. How to store JOPAMIRON

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light, heat and secondary X-rays.

JOPAMIRON should be used immediately following reconstitution and must not be stored.

6. Contents of the pack and other information

What JOPAMIRON contains

The active substance is iopamidol.

JOPAMIRON 300: Each 1 mL contains iopamidol 0,612 g in aqueous solution.

JOPAMIRON 370: Each 1 mL contains iopamidol 0,755 g in aqueous solution.

The other ingredients are calcium disodium edetate (dihydrate), trometamol, water for injections.

What JOPAMIRON looks like and contents of the pack

Clear, colourless solution.

Colourless glass bottle.

Pack sizes:

JOPAMIRON 300: Bottles of 50 mL, 100 mL and 200 mL.

JOPAMIRON 370: Bottles of 50 mL, 100 mL, 200 mL and 500 mL.

Not all pack sizes may be marketed.

Holder of the certificate of registration

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 in

To be allocated.

Registration numbers

JOPAMIRON 300 (50 mL): Q/28/202

JOPAMIRON 300 (100 mL): Q/28/203

JOPAMIRON 300 (200 mL): 59/28/0229

JOPAMIRON 370 (50 mL): Q/28/205

JOPAMIRON 370 (100 mL): Q/28/206

JOPAMIRON 370 (200 mL): 59/28/0230

JOPAMIRON 370 (500 mL): 59/28/0231

Date of registration

JOPAMIRON 300 (50 mL): 22 July 1983

JOPAMIRON 300 (100 mL): 22 July 1983

JOPAMIRON 300 (200 mL): 25 November 2025

JOPAMIRON 370 (50 mL): 22 July 1983

JOPAMIRON 370 (100 mL): 22 July 1983

JOPAMIRON 370 (200 mL): 25 November 2025

JOPAMIRON 370 (500 mL): 25 November 2025