

2025 04 IB Innovator update ZN12530-31  
2025 08 RFI

## **Package Leaflet: Information for the patient**

**Iohexol 300 mg I/ml solution for injection**  
**Iohexol 350 mg I/ml solution for injection**

**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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

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

### **1. What Iohexol is and what it is used for**

This medicine is for diagnostic use only. It is used only to help identify an illness. Iohexol is a ‘contrast medium’ It is given before an X-ray to make the picture that your doctor takes clearer.

- Once injected, it can help your doctor tell apart normal or abnormal appearance and shape of some organs in your body.
- It can be used for X-rays of your urinary system, spine or blood vessels, including blood vessels of your heart.
- Some other people are given this medicine before or during a scan of their head or body using ‘computed tomography’ (also called a CAT scan). This type of scan uses X-rays.
- It can also be used to look at your salivary glands, stomach and intestine, or for looking in body cavities, such as in your joints or womb and ovarian tubes.
- It can also be used in cases of mammography examinations

Your doctor or nurse will explain which part of your body will be scanned.

### **2. What you need to know before you are given Iohexol**

#### **Iohexol must not be given if you:**

- are allergic to iohexol, other iodine X-ray media, or any of the other ingredients of this medicine (listed in section 6).
- suffer from severe thyroid problems.

Consult your doctor or nurse if you are not sure.

### **Warnings and precautions**

Talk to your doctor or nurse before Iohexol is given to you if you:

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- have ever had an allergic reaction after a medicine similar to Iohexol, called a ‘contrast media’. In these cases it may be necessary to administer corticosteroids in advance (with an anti-inflammatory action) or antihistamines (medicines to treat allergy).
- have any thyroid problems.
- have ever had any allergies.
- have asthma or if you are using beta adrenergic blocking agents.
- have diabetes.
- have any brain disease or tumours.
- have or have had a severe heart disease (involving heart or blood vessels) including high blood pressure, blood clots, stroke and irregular heartbeat (arrhythmias).
- have kidney problems or both liver and kidney problems.
- have an illness called ‘myasthenia gravis’ (a condition causing severe muscle weakness).
- have a ‘phaeochromocytoma’ (constant or attacks of high blood pressure due to a rare tumour of your adrenal gland).
- have “homocystinuria” (a condition with increased excretion of the amino acid cysteine in urine)
- have any problems with your blood or bone marrow.
- have ever been dependent on alcohol or drugs.
- have epilepsy.
- are having a thyroid function test in the next weeks.

During or shortly after the imaging procedure you may experience a short-term brain disorder called contrast encephalopathy. Tell your doctor straight away if you notice any of the signs and symptoms related to this condition described in Section 4.

Contrast-enhanced mammography exposes you to higher levels of ionizing radiation than traditional mammography, however, it is still within the range defined by the international guidelines for mammography. Radiation dose depends on the thickness of the breast and the type of mammography machine used.

If you are not sure if any of the above apply to you, talk to your doctor before having Iohexol.

### **Thyroid disorders**

Thyroid disorders may be observed following administration of Iohexol 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 the administration of Iohexol.

### **Nervous system disturbances**

During or shortly after the imaging procedure you may experience a short-term brain disorder called encephalopathy. Tell your doctor or nurse straight away if you notice any of the signs and symptoms related to this condition described in section 4.

Make sure to drink plenty of fluid before and after receiving Iohexol. This applies especially to patients with multiple myeloma (white blood cells disease), diabetes, kidney problems, patients in bad general condition, children and elderly patients.

### **Children and adolescents**

Make sure your child drinks plenty of fluid before and after receiving Iohexol. This applies especially to infants and small children. Drugs that can damage the kidneys should not be taken at the same time as Iohexol (see “Warnings and Precautions”).

Iohexol may be removed from an infant’s body more slowly than an adult. Young infants (less than 1 year of age) and especially newly born are susceptible to changes in certain laboratory tests (in balance in salts and minerals) and circulatory changes in blood circulation (blood flow to the heart).

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### **Other medicines and Iohexol**

Please tell your doctor or nurse if you are diabetic and are taking any medicine containing metformin, or have recently taken any other medicines, including medicines obtained without a prescription or if you are using beta-blockers, vasoactive substances, ACE-enzyme inhibitors or angiotensin antagonists (medicines used to treat high blood pressure) or have recently been treated with interleukin-2 or interferons (medicines used to treat immune system diseases), neuroleptics or tricyclic antidepressants (medicines used to treat mental disorders like i.e. depression). This is because some medicines can affect the way Iohexol works.

Beta-blockers may increase your risk of experiencing breathing difficulties and may interfere with the treatment of severe allergic reactions, which is a risk of Iohexol.

Talk to your doctor or nurse before this medicine is given to you if you are not certain whether the above applies to you.

### **Pregnancy and breast-feeding**

You must tell your doctor or nurse if you are pregnant or think you may be pregnant. Your doctor will only use this product if it is considered that the benefit outweighs the risks for both the mother and the baby.

If Iohexol is given to the mother during pregnancy, the thyroid function of the newborn should be tested during the first week after birth. It is recommended that the testing is repeated again between 2 and 6 weeks of age in premature and low birth weight newborns.

Breast-feeding may be continued normally after an examination with Iohexol.

### **Driving and using machines**

Do not drive or use tools or machines after the last injection of Iohexol for:

- 24 hours, if it has been given into your spine, or one hour in all other cases.

This is because you may feel dizzy or have other signs of a reaction afterwards.

### **Important information about the ingredients of Iohexol**

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

## **3. How Iohexol is given**

Iohexol will always be given to you by a specially trained and qualified person.

- Iohexol will always be used in a hospital or clinic.
- They will tell you anything you need to know for its safe use.

Your doctor will decide the dose that is best for you.

#### **The usual dosage is:**

- one single injection or you may be asked to swallow it.

#### **After you have been given Iohexol**

You will be asked:

- to drink plenty of fluids afterwards (to help flush the medicine from your body), and
- to stay in or around the area where you had your scan or X-ray for around 30 minutes, and
- to stay in the clinic or hospital for one hour.

If you have any side effects during this time, tell your doctor or nurse straight away (see Section 4 'Possible Side Effects').

The advice above applies to all patients who have had Iohexol. If you are not sure about any of the above ask your doctor or nurse.

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Iohexol may be given in lots of different ways, a description of the ways it is usually given can be found below:

### **Injection into an artery or vein**

Iohexol will most commonly be injected into an arm vein or leg vein. Sometimes it will be administered using a thin plastic tube (catheter) introduced into an artery, usually in your arm or groin.

### **Injection into your spine**

Iohexol will be injected into the space around the spinal cord to see your spinal canal.

If you have been given Iohexol into your spine afterwards you will be asked to follow the advice below:

- to rest with your head and body upright for one hour, or six hours if you stay in bed, and
- to walk carefully and try not to bend down for six hours, and
- not to be completely alone for the first 24 hours after having Iohexol, if you are an outpatient and have ever had fits.

The advice above applies only if you have had Iohexol injected in to your spine.

If you are not sure about any of the above ask your doctor or nurse.

### **Use in your body cavities or joints**

Body cavities may be the joints, uterus and ovarian tubes. How and where Iohexol is given will vary.

### **Anal use**

For study of the gastrointestinal tract (stomach and intestine), this medicine is administered via the anus. It may be diluted with water before the study.

### **Use by mouth**

For examination of the gullet, stomach or small bowel Iohexol is normally given by mouth. Iohexol may be diluted with water for these examinations.

### **If you are given more Iohexol than you should**

Iohexol is administered in a hospital or clinic by a specially trained and qualified person. It is not probable that you will receive too much. Should this nonetheless occur, your doctor will treat you for this. In case of an overdose, mainly circulation disorders of the heart and lungs may occur. Sometimes kidney dialysis may be necessary as treatment to remove the excess iohexol from your body.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Allergic reactions**

**If you have an allergic reaction when you are in hospital or a clinic having Iohexol, tell your doctor or nurse straight away.**

The signs may include:

- wheeziness, difficulty in breathing or tightness or pain in your chest
- skin rash, lumps, itchy spots, blisters on the skin and in mouth, red/itchy eyes, cough, running nose, sneezing or other allergic (hypersensitivity) reactions which may be fatal (rare: may affect up to 1 in 1,000 people).

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- swelling of your face
- dizziness or feeling faint (caused by low blood pressure)
- severe skin reactions including potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Iohexol, you must not be re-started on Iohexol at any time.

The above side effects may happen several hours or days after Iohexol is given. If any of these side effects happen after you leave the hospital or clinic, **go straight to the casualty department of your nearest hospital.**

A short term decrease in formation of urine due to decreased kidney function is common after Iohexol is given. This may lead to damage to the kidney.

Other side effects that you may have are listed below; these depend on how or why Iohexol was given to you. Ask your doctor or nurse if you are not sure how you were given Iohexol.

**General** (Applies to all uses of Iohexol)

**Common:** may affect up to 1 in 10 people

- feeling hot

**Uncommon:** may affect up to 1 in 100 people

- feeling sick (nausea)
- increased/abnormal sweating, cold feeling, dizziness/fainting
- headache

**Rare:** may affect up to 1 in 1,000 people

- allergic (hypersensitivity) reactions (may be fatal)
- slow heart rate
- pain around your stomach area, vomiting, fever

**Very rare:** may affect up to 1 in 10,000 people

- momentary change in sense of taste
- high blood pressure, low blood pressure, shivering (chills)
- diarrhoea
- allergic reaction (may be life-threatening or fatal), including severe allergic reaction leading to shock and collapse, see 'Allergic reactions' above for other signs

**Not known:** frequency cannot be estimated from the available data

- painful swelling of the salivary glands (part inside the mouth where the saliva is produced).

**After injection into an artery or vein**

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**Common:** may affect up to 1 in 10 people

- short-term changes in breathing rate, respiratory problems

**Uncommon:** may affect up to 1 in 100 people

- pain and discomfort
- acute kidney injury

**Rare:** may affect up to 1 in 1,000 people

- diarrhoea
- irregular heartbeats, including fast heart rate
- cough, stopped breathing, fever, general discomfort
- dizziness, feeling weak, muscle weakness,
- intolerance for bright light
- feeling abnormally tired
- skin rash and itching, reddening of the skin
- reduced eyesight
- photophobia (“light sensitivity to eye”)

**Very rare:** may affect up to 1 in 10,000 people

- seizures (fits), clouding consciousness, stroke, disturbance of senses (like touch), trembling, stupor (“sleepy state”)
- flushing
- difficulty breathing
- myocardial infarction
- chest pain

**Not known:** frequency cannot be estimated from the available data

- severe skin reactions including severe rash, blistering and peeling of the skin
- feeling confused, feeling disorientated, feeling agitated, restless or anxious
- overactive thyroid gland (an excess of thyroid hormones in the blood causing a variety of symptoms, as e.g. rapid heartbeat, sweating, anxiety), short-term underactive thyroid gland (an abnormality of the thyroid function which later reverts to normal. Normally, no symptoms are seen)
- difficulty moving around for awhile
- speech disorders including aphasia (unable to speak), dysarthria (difficulties with pronouncing words)
- short-term blindness (hours to a few days), short-term hearing loss
- heart problems, including heart failure, spasms of the heart arteries and cyanosis (blue to purple colour of skin because of decreased oxygen)
- tightness in chest or troubled breathing, including swellings of the lungs, spasms in airways
- worsening of an inflammation of the pancreas (an organ behind the stomach) causing stomach pain that is worsened with eating
- pain and swelling in your vein, blood clots (thrombosis)
- joint pain, injection site reaction, back pain
- asthma attack
- psoriasis flare-up
- angioedema
- iodism (excessive amounts of iodine in the body) resulting in swelling and tenderness (pain) of your salivary glands
- memory loss (amnesia)
- short term brain disorder (contrast encephalopathy) which can cause headache, difficulties with vision, loss of vision, seizures, confusion, disorientation, drowsiness, loss of consciousness, coma, loss of coordination, loss of movement in one side of the body, problems with speech, memory loss and swelling of the brain
- thrombocytopenia (a condition where the platelet count is low causing the blood not to clot as well as

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it does normally)

- blood creatinine increased

### **After injection in your spine**

**Very common:** may affect more than 1 in 10 people

- headache (may be severe and lasting)

**Common:** may affect up to 1 in 10 people

- feeling sick (nausea), vomiting

**Uncommon:** may affect up to 1 in 100 people

- inflammation of the membranes that surround the brain and spinal cord

**Rare:** may affect up to 1 in 1,000 people

- seizures, dizziness
- pain in arms or legs, neck pain, back pain

**Not known:** frequency cannot be estimated from the available data

- feeling agitated
- feeling anxious
- feeling disorientated
- intolerance of bright light, neck stiffness
- difficulty moving around for a while, feeling confused
- disturbance of senses (like touch), short-term blindness (hours to a few days), short-term hearing loss
- tingling sensations, muscle contractions (spasms), injection site reaction
- short term brain disorder (contrast encephalopathy) which can cause headache, difficulties with vision, loss of vision, seizures, confusion, disorientation, drowsiness, loss of consciousness, coma, loss of coordination, loss of movement in one side of the body, problems with speech, memory loss and swelling of the brain.
- speech disorders including aphasia (unable to speak), dysarthria (difficulties with pronouncing words)

### **After use in body cavities**

(such as uterus and ovarian tubes, gall bladder and pancreas or hernia)

**Very common:** may affect more than 1 in 10 people

- pain around your stomach area

**Common:** may affect up to 1 in 10 people

- inflammation of the pancreas (an organ behind the stomach) causing stomach pain that is worsened with eating.
- abnormal amount of a substance produced by the pancreatic gland detected by lab investigation

**Not known:** frequency cannot be estimated from the data available

- pain

### **After injection into your joints**

**Very common:** may affect more than 1 in 10 people

- pain where it was injected

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**Not known:** frequency cannot be estimated from the available data

- inflammation of the joint

#### **After being given it by mouth**

**Very common:** may affect more than 1 in 10 people

- diarrhoea

**Common:** may affect up to 1 in 10 people nausea

- feeling sick (nausea), vomiting

**Uncommon:** may affect up to 1 in 100 people

- pain around your stomach area

If any of the side effects gets serious, or if you notice any side effects not listed, please tell your doctor or nurse.

#### **Additional side effects in children and adolescents:**

Short-term underactive thyroid gland (transient hypothyroidism) has been reported in premature infants, neonates and in other children after receiving Iohexol. Premature infants are particularly sensitive to the effect of iodine. Thyroid function should be checked in neonates during the first week of life, following administration of iodinated contrast agents to the mother during pregnancy. Repeat testing of thyroid function is recommended at 2 to 6 weeks of age, particularly in low birth weight newborn or premature newborn.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Iohexol**

Keep this medicine out of the sight and reach of children.

Keep the container in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the vial after EXP. The expiry date refers to the last day of that month.

The solution of contrast medium should be drawn into the syringe or infusion bottle connected to the equipment only immediately before the test.

The vials containing the solutions of contrast media are intended for single use only.

Any portions contrast medium solution not used in examination must be discarded.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Iohexol contains**

- The active substance is iohexol. Each vial contains 647 mg iohexol per ml (corresponding with 300 mg iodine per ml), or 755 mg iohexol per ml (corresponding with 350 mg iodine per ml).

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- The other ingredients are trometamol, sodium calcium edetate, hydrochloric acid, sodium hydroxide, and water for injection.

**What Iohexol looks like and contents of the pack**

Iohexol is a solution for injection and is available in two concentrations:

Iohexol 300 mg I/ ml, solution for injection – type I glass vials, 50 ml and 100 ml.

Iohexol 350 mg I/ ml, solution for injection – type I glass vials, 50 ml and 100 ml.

The vials of this product are available in packs of 10.

Not all pack sizes may be marketed.

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