

Package leaflet: Information for the patient

Iovision 350 mg I/mL solution for injection iohexol

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Iovision is and what it is used for

Iovision contains the active substance iohexol. This medicine is for diagnostic use only. It is used only to help identify an illness.

Iovision 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.

The medicine can be used for X-rays of your:

- blood vessels of the heart and other parts of the body (except those of the brain)
- urinary system
- joints
- gastrointestinal tract
- stomach and intestine
- head or body using 'computed tomography' (also called a CAT scan)
- breast using contrast-enhanced angiommammography in adults

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

2. What you need to know before you use Iovision

Do not use Iovision

- if you are allergic to the active substance, to any other iodinated X-ray contrast media, or to any of the other ingredients of this medicine (listed in section 6);
- if you have ever had a severe skin reaction (either immediately or days after the injection) after receiving this type of iodinated contrast medium (Iohexol);
- if you have an overactive thyroid gland (thyrotoxicosis);

Warnings and precautions

Talk to your doctor before using Iovision:

- If you have ever had an allergic reaction after a medicine similar to Iovision, called a ‘contrast medium’. (The signs of an allergic reaction may include one or more of the following; wheeziness, difficulty in breathing tightness or pain in your chest, skin rash, lumps, itchy spots, blisters on skin and in mouth, red/itchy eyes, cough, running nose, sneezing or other allergic symptoms, swelling of your face, dizziness or feeling faint caused by low blood pressure).
- If you have any thyroid problems.
- If you have ever had any allergies.
- If you have asthma.
- If you have diabetes.
- If you have any brain disease; for example tumours, swelling or inflammation of the brain, or any condition involving the blood vessels in the brain, including blood clot or bleeding.
- If you have or have had severe cardiac disease (involving heart or blood vessels) including high blood pressure, blood clots, stroke and irregular heartbeats (arrhythmias).
- If you have kidney problems or both liver and kidney problems.
- If you have an illness called ‘myasthenia gravis’ (a condition causing severe muscle weakness).
- If you have a ‘phaeochromocytoma’ (constant or attacks of high blood pressure due to a rare tumour of your adrenal gland).
- If you have “homocystinuria” (a condition with increased excretion of the amino acid cysteine in urine)
- If you have any problems with your blood or bone marrow.
- If you have an immune system disease
- If you have ever been dependent on alcohol or drugs.
- If you have epilepsy.
- If you are having a thyroid function test in the next weeks.
- If you have pulmonary hypertension (high blood pressure in the arteries to your lungs)
- If you have paraproteinaemias (the presence of excessive amount of an abnormal protein in your blood)
- If you are having blood or urine samples taken on the same day

Angiommography with contrast enhancement exposes you to higher levels of ionizing radiation than traditional mammography. However, the level of exposure is always within the interval defined by the international guidelines for mammography. The dose of radiation depends on the thickness of the breast and the type of mammography device used.

If you are not sure if any of the above apply to you, talk to your doctor before having Iovision. Make sure to drink plenty of fluid before and after receiving Iovision. This applies especially to patients with multiple myeloma (white blood cells disease), diabetes, kidney problems, patients in bad general condition, children and elderly patients.

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 signs and symptoms related to this condition described in Section 4.

Thyroid disorders may be observed following administration of Iovision 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 Iovision.

Children and adolescents

- Make sure to drink plenty of fluid before and after receiving Iovision. This applies especially to infants and small children.
- Drugs that can damage the kidneys should not be taken at the same time as Iovision.
- Iovision 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).

Other medicines and Iovision

Tell your doctor if you are taking, have recently taken or might take any other medicines, including:

- containing metformin (medicine used by diabetics);
- radioactive substances (called radiopharmaceuticals), for example to examine your thyroid or kidneys
- medicines used to treat high blood pressure disease (beta-blockers, vasoactive substances, ACE inhibitors or angiotensin antagonists);
- medicines that make you pass urine more often (*diuretics*)
- interleukin-2 or interferons (medicines used to treat immune system diseases);
- antidepressants (medicines used to treat mental disorders like depression).

This is because some medicines can affect the way Iovision works.

Certain drugs used to treat high blood pressure (beta-blockers) may increase your risk of experiencing breathing difficulties and may interfere with the treatment of severe allergic reactions. This is a risk of Iovision.

Laboratory tests

Tell the doctor or nurse that you have been given Iovision if you are asked to provide a sample of your blood or urine for any laboratory examinations on the same day as your scan and several weeks after. This is because Iovision may interfere with the results for some laboratory tests.

Pregnancy and breast-feeding

- You must tell your doctor 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 risk for both the mother and the baby.
- If Iovision has been given to the mother during pregnancy, it is recommended to monitor the infants thyroid function (see 'Warnings and precautions').
- Breast-feeding may be continued normally after an examination with Iovision.

Driving and using machines

Do not drive or use tools or machines after your last injection of Iovision for one hour.

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

Iovision contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per mL and is therefore essentially "sodium-free".

3. How to use Iovision

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

- Iovision will always be used in a hospital or clinic.

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

The usual dose is:

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

Iovision 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

Iovision will most commonly be injected into an arm vein or leg vein. Sometimes it will be given through a thin plastic tube (catheter), inserted into an artery usually in your arm or groin.

Use in your body cavities or joints

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

Use by mouth

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

After you have been given Iovision

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. However, delayed reactions may occur.

If you have any side effects during this time, tell your doctor straight away (see Section 4 ‘Possible side effects’).

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

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 Iovision, tell the doctor straight away. The signs may include:

- wheeziness, difficulty in breathing or tightness or pain in your chest
- skin rash, lumps, itchy spots, blisters on skin and in mouth, red/itchy eyes, cough, running nose, sneezing or other allergic symptoms
- swelling of your face
- dizziness or feeling faint (caused by low blood pressure)

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

Severe skin reactions

If you develop any of the following very rare syndromes, you should contact a doctor immediately.

Stevens-Johnson Syndrome:

- An extremely severe allergic reaction with a skin rash usually in the form of blisters or sores in the oral cavity and eyes and other mucous membranes, such as genitals

Toxic epidermal necrolysis:

- Severe widespread skin damage (skin detachment of the epidermis and superficial mucous membranes)

Acute generalised exanthematous pustulosis

- Sudden widespread rash with small pus-filled blisters (pustules), often with fever

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

General

(applies to all uses of Iovision)

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

- 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 or low blood pressure, shivering (chills)
- diarrhoea
- fainting or feeling faint (vasovagal reaction)

Not known: frequency cannot be estimated from the available data

- swelling and tenderness (pain) of your salivary glands

After an injection into an artery or vein

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 slow or fast heart rate
- cough, stopped breathing, fever, general discomfort
- dizziness, feeling weak, muscle weakness
- intolerance to bright light
- feeling abnormally tired
- skin rash and itching, reddening of the skin
- reduced eyesight (including double vision, blurred vision)

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

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

Not known: frequency cannot be estimated from the available data

- 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 heart beat, sweating, anxiety), short-term underactive thyroid gland (an

abnormality of the thyroid function which later reverts to normal)

- difficulty moving around for a while
- 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, arrest of the heart, spasms of the heart arteries and cyanosis (blue to purple colour of skin because of decreased oxygen)
- tightness in chest or troubled breathing including swelling of the lungs, spasms in the airways
- worsening of an inflammation of the pancreas (an organ behind the stomach) causing stomach pain that is worsened with eating
- pain and swelling of your vein, blood clots (thrombosis)
- joint pain, injection site reaction, back pain
- psoriasis flare-up
- asthma attack
- iodism (excessive amounts of iodine in the body) resulting in swelling and tenderness (pain) of your salivary glands
- short term brain disorders (encephalopathy) which can cause confusion, hallucinations, difficulties with vision, loss of vision, seizures, loss of coordination, loss of movement in one side of the body, problems with speech, and loss of consciousness, including short term memory loss, coma and stupor ("sleepy state")
- thrombocytopenia (a condition where the platelet count is low causing the blood not to clot as well as it does normally)
- blood creatinine increased

After use in body cavities

See the general side effects listed above.

After being given it by mouth

Very common: may affect more than 1 in 10 people

- diarrhoea
- lower abdominal pain
- pain

Common: may affect up to 1 in 10 people

- 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.

Additional side effects in children and adolescents

A short-term abnormality of the thyroid function which later reverts to normal (transient hypothyroidism) has been reported in premature infants, neonates and in other children after receiving Iovision. Normally, no symptoms are seen. Premature infants are particularly sensitive to the effect of iodine.

A short-term abnormality of the thyroid function which later reverts to normal (transient hypothyroidism) has been reported in a premature breast fed infant. The nursing mother was repeatedly exposed to Iovision.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#).*

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

5. How to store Iovision

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

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

Keep the bottle in the outer carton in order to protect from light and secondary X-rays.

The product may be stored unopened in the original container at 37 °C for up to 1 months. After this period the solution has to be discarded, even though the shelf life of the products mentioned on the container and carton box has not been reached.

After first opening (200 mL/500 mL bottles): Chemical and physical in-use stability has been demonstrated at 25°C for 48 hours and at 37°C for 24 hours.

From a microbial point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are in the responsibility of the user and would normally not be longer than 24 hours at 25 °C or 37 °C unless the handling has taken place in controlled and validated aseptic conditions.

Do not throw away any medicines via wastewater or household waste. 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 Iovision contains

The active substance is iohexol:

Iovision 350 mg I/mL contains 350 mg iodine per mL (equivalent to 755 mg iohexol per mL).

The excipients are: trometamol, sodium-calcium edetate, concentrated hydrochloric acid (for pH adjustment), water for injections.

What Iovision looks like and contents of the pack

Iovision is a solution for injection. The medicine is clear, colourless to light yellow solution, without visible particles.

The medicine is provided in clear glass bottles (glass type II) closed with chlorobutyl rubber stopper and an aluminium cap.

Iovision 350 mg I/mL is supplied in packs containing 10 bottles with 75, 100 or 200 mL or five bottles with 500 mL.

The 75 mL and 100 mL bottles are for single use only.

The 200 mL bottle is for single use and for multi-dose use in multiple patients.

The 500 mL bottle is for multi-dose use in multiple patients.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>
{Name and address}

<{tel}>
<{fax}>
<{e-mail}>

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden	Iovision 350 mg I/mL injektionsvätska, lösning
France	IOSAJEM 350 mg d'I/mL, solution injectable

This leaflet was last revised in
2025-12-11