Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Iohexol 240 mg I/ml solution for injection
Iohexol 300 mg I/ml solution for injection
Iohexol 350 mg I/ml solution for injection

iohexol

PL 41203/0012, 0014, 0015

Elara Pharmaservices Limited

LAY SUMMARY

Iohexol 240 mg I/ml solution for injection
Iohexol 300 mg I/ml solution for injection
Iohexol 350 mg I/ml solution for injection
iohexol

This is a summary of the Public Assessment Report (PAR) for Iohexol 240 mg I/ml, 300 mg I/ml, and 350 mg I/ml solution for injection. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Iohexol in this lay summary for ease of reading.

For practical information about using Iohexol, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Iohexol and what is are they used for?
These products are generic medicines. This means that these medicines are the same as, and considered interchangeable with, a reference medicines already authorised, called Omnipaque Injection 240 mg I/ml, 300 mg I/ml, and 350 mg I/ml solution for injection.

These medicines are for diagnostic use *only*. They are used only to help identify an illness.

Iohexol are 'contrast medium'. They are given before an X-ray to make the picture that the patient's doctor takes clearer.

- Once injected, these can help the patient's doctor tell apart normal or abnormal appearance and shape of some organs in their body.
- They can be used for X-rays of the patient's urinary system, spine or blood vessels, including blood vessels of their heart.
- Some other people are given these medicines 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.
- They can also be used to look at the patient's salivary glands, stomach and intestine, or for looking in body cavities, such as in their joints or womb and ovarian tubes.
- They can also be used in cases of mammography examinations.

The patient's doctor will explain which part of their body will be scanned.

How do Iohexol work?
Iohexol contain the active substance, iohexol which is an iodinated X-ray contrast media.

How are Iohexol used?
The pharmaceutical form of these medicines is a solution for injection and the route of administration is intravenous (into a vein), intra-arterial (into an artery) and intrathecal (into the spinal canal) use.

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

- Iohexol will always be used in a hospital or clinic.
- The patient will be informed of anything they need to know for its safe use.

The patient's doctor will decide the dose that is best for them.

Iohexol will be given to the patient as one single injection or they may be asked to swallow it.

After the patient has been given Iohexol, they will be asked:

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

If the patient has any side effects during this time, they should tell their doctor straight away. The advice above applies to all patients who have had Iohexol. If they are not sure about any of the above, they should ask their doctor.

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 given through a thin plastic tube (catheter), inserted into an artery usually in the patient's arm or groin.

Injection into the patient's spine
Iohexol will be injected into the space around the spinal cord to see the patient's spinal canal. If they have been given Iohexol into their spine, they will be asked to follow the below advice afterwards:

- to rest with their head and body upright for one hour, or six hours if they 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 they are an outpatient and have ever had fits.

The advice above applies only if the patient has had Iohexol injected into their spine. If they are not sure about any of the above, they should ask their doctor.

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

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.

For further information on how Iohexol are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patient should ask the administering healthcare practitioner if they have any questions concerning their medicine.

What benefits of Iohexol have been shown in studies?
Iohexol are generic medicines that fulfils criteria meaning that no additional studies are required. Iohexol have been considered generic medicines of the reference medicines based on a comparison of their physical and chemical characteristics.

What are the possible side effects of Iohexol?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of these medicines.

Because Iohexol are generic medicines, their benefits and possible side effects are considered to be the same as for the reference medicines.

Why were Iohexol approved?
It was concluded that, Iohexol have been shown to be comparable to the reference medicines. Therefore, the MHRA decided that, as for the reference medicines, the benefits are greater than the risks and authorised that these can be approved for use.

What measures are being taken to ensure the safe and effective use of Iohexol?
As for all newly authorised medicines, a Risk Management Plan (RMP) has been developed for Iohexol. The RMP details the important risks of Iohexol, how these risks can be minimised, any uncertainties about Iohexol (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Iohexol:

Summary of safety concerns	
Important risks identified	– Hypersensitivity – Coagulopathy – Use in patients with cardio-circulatory disease – Use in patients with cerebral pathologies – Use in patients with renal and hepatic impairment – Aggravation of symptoms of myasthenia gravis – Use in patients with disturbed thyroid function – Concomitant use with Metformin – Serious vasculitis or Stevens-Johnson-like syndromes – Hypersensitive crisis in patients suffering from Phaeochromocytoma

	– Sickle cell disease – Extravasation – Use in paediatric patients
Important potential risk	– None
Missing information	– Use in pregnancy and lactation

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Iohexol are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Iohexol
Marketing authorisations for Iohexol were granted in the United Kingdom (UK) on 25 April 2025.

The full PAR for Iohexol follows this summary.

This summary was last updated in June 2025.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) approved the applications for Iohexol 240 mg I/ml, 300 mg I/ml, and 350 mg I/ml solution for injection (PL 41203/0012, 0014, 0015).

The products are approved for the following indications:
X-ray contrast medium for use in adults and children for urography, phlebography, i.v. DSA, CT, arteriography, cardioangiography and i.a. DSA. Myelography. For use in body cavities: Arthrography, ERP/ERCP, herniography, hysterosalpingography, sialography and use in the G-I tract. Contrast-enhanced mammography (CEM) in adults to evaluate and detect known or suspected lesions of the breast, as an adjunct to mammography (with or without ultrasound) or as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or unavailable.

These medicinal products are for diagnostic use *only*.

Iohexol 240 mg I/ml, 300 mg I/ml, and 350 mg I/ml solution for injection contain the active substance, iohexol.

For most of the haemodynamic, clinical-chemical and coagulation parameters examined following intravenous injection of iohexol in healthy volunteers, no significant deviation from preinjection values has been found. The few changes observed in the laboratory parameters were minor and considered to be of no clinical importance.

These applications were approved under Regulation 51B of The Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended), as generic medicines of suitable originator medicinal products, Omnipaque Injection 240 mg I/ml, 300 mg I/ml, and 350 mg I/ml solution for injection, that have been licensed for a suitable time, in line with the legal requirements.

No new non-clinical studies were conducted, which is acceptable given that the applications are for generic medicinal products of suitable reference products.

A biowaiver was submitted with these applications, which was accepted. A bioequivalence study was not necessary to support this application for a parenteral product and the applicant submitted none. According to CPMP guidelines, bioequivalence studies are not generally required for parenteral aqueous solutions (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**, Guideline on the Investigation of Bioequivalence). No new clinical studies were provided with these applications.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Marketing authorisations for Iohexol 240 mg I/ml, 300 mg I/ml, and 350 mg I/ml solution for injection were granted in the United Kingdom (UK) on 25 April 2025.

II. QUALITY ASPECTS

II.1 Introduction

The active substance is iohexol.
Three different strengths of the solution for injection are available.
Each 240 mg I/ml solution for injection contains 518 mg iohexol per ml (equivalent to 240 mg iodine per ml), each 300 mg I/ml solution for injection contains 647 mg iohexol per ml (equivalent to 300 mg iodine per ml), and each 350 mg I/ml solution for injection contains 755 mg iohexol per ml (equivalent to 350 mg iodine per ml).

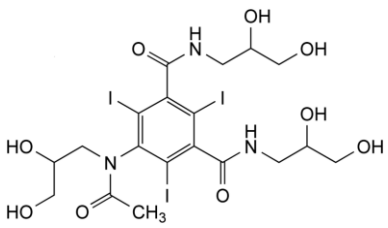
In addition to iohexol, these products also contain the following excipients:
sodium calcium edetate, trometamol, hydrochloric acid diluted and water for injection.

The finished products are packaged in the following:
240 mg I/ml
50 mL and 100 mL glass bottles closed with rubber stoppers and aluminium seals with a plastic cap and are available in a pack-size of 1 bottle.
300 mg I/ml
20 mL, 50 mL and 100 mL glass bottles closed with rubber stoppers and aluminium seals with a plastic cap and are available in pack-sizes of 1 or 10 bottles.
350 mg I/ml
20 mL, 50 mL and 100 mL glass bottles closed with rubber stoppers and aluminium seals with a plastic cap and are available in pack-sizes of 1 or 6 bottles.
Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current regulations concerning materials in contact with food.

II.2 ACTIVE SUBSTANCE

rINN: iohexol
Chemical Name: 5-[Acetyl(2,3-dihydroxypropyl)amino]-*N*,*N*′-bis(2,3-dihydroxypropyl)-2,4,6-triiodobenzene-1,3-dicarboxamide.
Molecular Formula: $C_{19}H_{26}I_3N_3O_9$
Chemical Structure:



Molecular Weight: 821
Appearance: White or greyish-white, hygroscopic powder.
Solubility: Very soluble in water, freely soluble in methanol, practically insoluble in methylene chloride.

Iohexol is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 DRUG PRODUCTS

Pharmaceutical development

A satisfactory account of the pharmaceutical development was provided.

All excipients comply with either their respective European/national monographs, or a suitable in-house specification. Satisfactory Certificates of Analysis were provided for all excipients.

No excipients of animal or human origin are used in the final products.

These products do not contain or consist of genetically modified organisms (GMO).

Manufacture of the products

A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulation data have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specifications

The finished product specifications at release and shelf-life are satisfactory. The test methods have been described and adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

Stability

Finished product stability studies have been conducted in accordance with current guidelines, using batches of the finished product stored in the packaging proposed for marketing. Based on the results, a shelf-life of 2 years, with the storage conditions ‘Store in the original package in order to protect from light’, is acceptable.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The grant of marketing authorisations was recommended.

III. NON-CLINICAL ASPECTS

III.1 Introduction

As the pharmacodynamic, pharmacokinetic and toxicological properties of iohexol are well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

III.2 Pharmacology

No new pharmacology data were provided, and none were required for these applications.

III.3 Pharmacokinetics

No new pharmacokinetic data were provided, and none were required for these applications.

III.4 Toxicology
No new toxicology data were provided, and none were required for these applications.

III.5 Ecotoxicity/Environmental Risk Assessment
A suitable justification was provided for non-submission of an Environmental Risk Assessment. As the applications are for generic versions of an already authorised products, an increase in environmental exposure is not anticipated following approval of the marketing authorisations for the proposed products.

III.6 Discussion on the non-clinical aspects
The grant of marketing authorisations was recommended.

IV. CLINICAL ASPECTS

IV.1 Introduction
The clinical pharmacology, efficacy and safety of iohexol are well-known. According to the regulatory requirements, the applicant has provided a suitable biowaiver and a bioequivalence study is not required for this product. An overview based on a literature review is, thus, satisfactory.

IV.2 Pharmacokinetics
No new pharmacokinetic data were submitted for these applications and none were required.

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted for these applications and none were required.

IV.4 Clinical efficacy
No new efficacy data were submitted with these applications and none were required.

IV.5 Clinical safety
No new safety data were submitted with these applications and none were required. The safety profile for these products is considered to be the same as Omnipaque Injection 240 mg I/ml, 300 mg I/ml, and 350 mg I/ml solution for injection.

IV.6 Risk Management Plan (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

IV.7 Discussion on the clinical aspects
The grant of marketing authorisations was recommended for these applications.

V. USER CONSULTATION
A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with iohexol is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the reference products.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or Reference Regulator (RR) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	Scope	Product information affected	Date of grant	Outcome	Assessment report attached Y/N