LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Iovision
# (iohexol)

# SE/H/2575/01-02/DC

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# Summary Public Assessment Report

Iovision
iohexol

Solution for injection, 300 mg I/ml, 350 mg I/ml

This is a summary of the public assessment report (PAR) for Iovision. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Iovision and what is it used for?**

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called OMNIPAQUE.

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

**How does Iovision work?**

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.

**How is Iovision used?**
The pharmaceutical form is solution for injection.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

**What benefits of Iovision have been shown in studies?**

No additional studies were needed as the product is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, OMNIPAQUE.

**What are the possible side effects from Iovision?**

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

**Why is Iovision approved?**

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for OMNIPAQUE, the benefits are greater than its risks and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Iovision?**
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

For more details, please see the full PAR for Iovision on the following website: MRI - Home.

**Other information about Iovision**
The full PAR for Iovision can be found on the following website: MRI - Home. For more information about treatment with Iovision, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-03.