# Summary of risk management plan for Iovision 300 mg I/mL and 350 mg I/mL solution for injection (Iohexol)

This is a summary of the risk management plan (RMP) for Iovision 300 mg I/mL and 350 mg I/mL solution for injection. The RMP details important risks of Iovision 300 mg I/mL and 350 mg I/mL solution for injection, how these risks can be minimised, and how more information will be obtained about Iovision 300 mg I/mL and 350 mg I/mL solution for injection's risks and uncertainties (missing information).

Iovision 300 mg I/mL and 350 mg I/mL solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Iovision 300 mg I/mL and 350 mg I/mL solution for injection should be used.

Important new concerns or changes to the current ones will be included in updates of Iovision 300 mg I/mL and 350 mg I/mL solution for injection's RMP.

## I. The medicine and what it is used for

Iovision 300 mg I/mL and 350 mg I/mL solution for injection is an X-ray contrast medium for use in adults and children indicated for

cardioangiography, arteriography, urography, phlebography and CT-enhancement. Lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection. Arthrography, endoscopic retrograde pancreatography, (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography and studies of the gastrointestinal tract, as well as

contrast-enhanced angiomammography in adults to assess and detect known or suspected breast lesions, as an adjunct to mammography (with or without ultrasound) or as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or unavailable.

(see SmPC for the full indication).

It contains Iohexol as the active substance and it is given by intravenous, intra-arterial and intrathecal route, use in body cavities.

## II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Iovision 300 mg I/mL and 350 mg I/mL solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Iovision 300 mg I/mL and 350 mg I/mL solution for injection's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Iovision 300 mg I/mL and 350 mg I/mL solution for injection is not yet available, it is listed under 'missing information' below.

## *II.A List of important risks and missing information*

Important risks of Iovision 300 mg I/mL and 350 mg I/mL solution for injection are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Iovision 300 mg I/mL and 350 mg I/mL solution for injection. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | • None |
| Important potential risks | • None |
| Missing information | • None |

## *II.B Summary of important risks*

The safety information in the proposed Product Information is aligned to the reference medicinal product.

## *II.C Post-authorisation development plan*

### II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Iovision 300 mg I/mL and 350 mg I/mL solution for injection.

### II.C.2 Other studies in post-authorisation development plan

There are no studies required for Iovision 300 mg I/mL and 350 mg I/mL solution for injection.