Summary of the risk management plan for Iomeron (Iomeprol)

This is a summary of the RMP for Iomeron. The RMP details important risks of Iomeron, how these risks can be minimised, and how more information will be obtained about the Iomeron risks and uncertainties.

The Iomeron SmPC and its package leaflet give essential information to healthcare professionals and patients on how Iomeron should be used.

Important new concerns or changes to the current ones will be included in updates of the Iomeron RMP.

VI.I The medicine and what it is used for

Iomeron is authorised for a variety of diagnostic X-ray imaging procedures, including angiography, CT, intravenous excretory urography, and myelography (see SmPC for the full list of indications).

It contains Iomeprol as the active substance and it is given by intravenous, intra-arterial, intrathecal or intracavitary routes of administration.

This medicinal product is for diagnostic use only.

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

Important risks of Iomeprol together with measures to minimise such 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.

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

VI.IIA List of important risks and missing information

Important risks of Iomeron 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 Iomeron. 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	• Hypothyroidism in paediatric patients younger than 3 years of age
Important potential risks	• None
Missing information	• None

VI.IIB Summary of important risks

Important identified risk: Hypothyroidism in paediatric patients younger than 3 years of age	
Evidence for linking the risk to the medicine	Integrated clinical trial database, post-marketing safety database, literature
Risk factors and risk groups	No particular group has been identified in the clinical safety database to be at increased risk of developing hypothyroidism after Iomeprol exposure. There is literature evidence that hypothyroidism or transient thyroid suppression may be observed after exposure to iodinated contrast media. Special attention should be paid to paediatric patients below 3 years of age because an incident of underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient T4 replacement therapy. The incidence of hypothyroidism in patients younger than 3 years of age exposed to iodinated contrast media has been reported between 1.3% and 15%, depending on the age of the subjects and the dose of the iodinated contrast agent, and is more commonly observed in neonates and premature infants.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 and 4.8 Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: a) Collection, review and submission of spontaneous reports of hypothyroidism from all sources. b) Ongoing monitoring of hypothyroidism reports with regular *ad-hoc*

Important identified risk: Hypothyroidism in paediatric patients younger than 3 years of age	
	and aggregate reports. c) Regular and *ad-hoc* signal detection and evaluation activities.

VI.IIC Post-authorisation development plan

VI.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 Iomeprol.

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

There are no studies required for Iomeprol.