SUMMARY OF RISK MANAGEMENT PLAN FOR ULTRAVIST® (IOPROMIDE)

This is a summary of the risk management plan (RMP) for Ultravist. The RMP details important risks of Ultravist, how these risks can be minimized, and how more information will be obtained about Ultravist's risks and uncertainties (missing information).
Ultravist's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ultravist should be used.

This summary of the RMP for Ultravist should be read in the context of all other information including the assessment report of the evaluation and its plain language summary, all of which is part of the Public Assessment Report where available.

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

I. The medicine and what it is used for

Ultravist is authorized for diagnostic use only. Ultravist is indicated for intravascular use and use in body cavities for the following procedures: angiography and urography, digital subtraction angiography, CT for contrast medium enhancement, arthrography and hysterosalpingography. It is a contrast-enhancing substance (see the SmPC for the full indication). It contains iopromide as the active substance and it is given as a solution for injection/infusion.

II. Risks associated with the medicine and activities to minimize or further characterize the risks.

Important risks of Ultravist, together with measures to minimize such risks and the proposed studies for learning more about Ultravist's risks, are outlined below.

Measures to minimize 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 authorized 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 public (e.g. with or without prescription) can help to minimizes its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Ultravist 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 Ultravist. 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 children below 3 years of age
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Hypothyroidism in children below 3 years of age	
Evidence for linking the risk to the medicine	Exposure to iodinated contrast media (ICM) may be associated with development of hypothyroidism presumably due to the presence of free iodide in the ICM solution. The normal response to a high iodine load is the acute Wolff-Chaikoff effect, a rapid inhibition of thyroid hormone synthesis and release. Following several days of continued exposure to high iodine levels, there is an escape from the acute Wolff-Chaikoff effect. Failure to escape from the acute Wolff-Chaikoff effect results in iodine-induced hypothyroidism.
Risk factors and risk groups	The risk factors associated with development of hypothyroidism in children include: younger age, very low birth weight, prematurity, presence of other conditions, such as, admission to neonatal or paediatric intensive care units, cardiac conditions, and renal impairment. Paediatric patients with cardiac conditions may be at the greatest risk given that they often require high doses of contrast during invasive cardiac procedures, such as catheterization and computed tomography (CT).
Risk minimisation measures	**Routine risk communication:** • SmPC section 4.2

	Routine risk communication recommending specific clinical measure to address the risk: • SmPC section 4.4 where advice is given to evaluate thyroid function in paediatric patients younger than 3 years of age. **Other routine risk minimization measures beyond the Product Information:** • Ultravist is administered by and under the supervision of qualified healthcare professionals.
Additional pharmacovigilance activities	None

B Important potential risks	
Evidence for linking the risk to the medicine	N/A
Risk factors and risk groups	N/A
Risk minimization measures	N/A
Additional pharmacovigilance activities	N/A

C Missing information	
Evidence for linking the risk to the medicine	N/A
Risk factors and risk groups	N/A
Risk minimization measures	N/A
Additional pharmacovigilance activities	N/A

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization.

No studies are conditions of the marketing authorization or specific obligations of Ultravist.

II.C.2 Other studies in post-authorization development plan

Not applicable.