Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for gadoteric acid 0.0025 mmol/ml. This RMP details important risks of gadoteric acid, and how additional information will be obtained about the risks and uncertainties (missing information).

Moreover, gadoteric acid summary of product characteristics (SmPC) and its package information leaflet (PIL) provide essential information to healthcare professionals and patients on how the product should be used.

I. The medicine and what it is used for

Dotarem Arthro® is a paramagnetic contrast agent. The active ingredient is Gadoteric acid at a concentration of 0.0025 mmol/ml (equivalent to 1.397 mg/ml). It is intended for use in direct magnetic resonance arthrography and should be used only when diagnostic information is essential and not available with unenhanced MRI. It does not have a specific pharmacodynamics activity and is very inert biologically.

Gadoteric acid is a solution for injection, for diagnosis only. The recommended dose depends on the region examined and the size of the joint.

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

Important risks of gadoteric acid, together with measures to minimise such risks and the proposed studies for learning more about gadoteric acid risks, are outlined below.
Measures to minimise the risks identified for gadoteric acid can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the SmPC and PIL 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 analyzed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

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

II.A List of important risks and missing information

Summary of safety concerns	
Important identified risks	- None
Important potential risks	- None
Missing information	- None

II.B Summary of important risks

- **Risks relating to the active substance**

Not applicable.

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 any specific obligation with regards to gadoteric acid.

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

There are no post-authorisation development studies required for gadoteric acid.