Summary of risk management plan for Oxybutynin MEDICE® 0.1%, 1 mg/ml intravesical solution (oxybutynin hydrochloride)

This is a summary of the risk management plan (RMP) for Oxybutynin MEDICE® 0.1%. The RMP details important risks of Oxybutynin MEDICE® 0.1%, how these risks can be minimised, and how more information will be obtained about Oxybutynin MEDICE® 0.1%'s risks and uncertainties (missing information).

Oxybutynin MEDICE® 0.1%'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Oxybutynin MEDICE® 0.1% should be used.

I. The medicine and what it is used for

Oxybutynin MEDICE® 0.1% is authorised for the suppression of detrusor overactivity due to spinal cord injury or myelomeningocele (spina bifida) in children from 6 years of age and adults, who are managing bladder emptying by clean intermittent catheterisation, not adequately managed with oral anticholinergics (see SmPC for the full indication). It contains oxybutynin hydrochloride as the active substance and it is given by intravesical instillation.

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

Important risks of Oxybutynin MEDICE® 0.1%, together with measures to minimise such risks and the proposed studies for learning more about Oxybutynin MEDICE® 0.1%'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*.

II.A List of important risks and missing information

Important risks of Oxybutynin MEDICE® 0.1% 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 Oxybutynin MEDICE® 0.1%. 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

Not applicable as there are no important risks.

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 Oxybutynin MEDICE® 0.1%.

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

There are no studies required for Oxybutynin MEDICE® 0.1%.