Summary of risk management plan for

Oxybutynin hydrochloride 1 mg/ml, intravesical solution

(Oxybutynin hydrochloride)

This is a summary of the risk management plan (RMP) for Oxybutynin hydrochloride 1 mg/ml, intravesical solution. The RMP details important risks of the product, how these risks can be minimised, and how more information will be obtained about the risks and uncertainties (missing information) of the product.

The summary of product characteristics (SmPC) and the package leaflet (PL) of Oxybutynin hydrochloride 1 mg/ml, intravesical solution give essential information to healthcare professionals and patients on how the product should be used.

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

I. The medicine and what it is used for

Oxybutynin hydrochloride 1 mg/ml, intravesical solution is authorised for the suppression of neurogenic detrusor overactivity (NDO) in children from 6 years of age and in adults who are managing their bladder emptying by clean intermittent catheterisation (CIC), if they cannot be adequately managed using oral anticholinergics due to lack of efficacy and/or intolerable side effects. 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 hydrochloride 1 mg/ml, intravesical solution, together with measures to minimise such risks and the proposed studies for learning more about these 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 hydrochloride 1 mg/ml, intravesical solution 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 the product. 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

Important identified risks

None

Important potential risks

None

Missing information

None

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 hydrochloride 1 mg/ml, intravesical solution.

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

There are no studies required for Oxybutynin hydrochloride 1 mg/ml, intravesical solution.