Part VI: Summary of the risk management plan

Summary of risk management plan for Oxybutynin Macure

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

Oxybutynin Macure summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Oxybutynin Macure should be used.

I. The medicine and what it is used for

Oxybutynin Macure is authorised for treatment of

Adults:

- Frequent and severe urinary urgency or urge incontinence in an unstable urinary bladder.
- Neurogenic bladder disorders, e.g. uninhibited bladder and reflex bladder.

Children older than 5 years:

- Urinary incontinence, frequent and severe urinary urgency in an unstable bladder caused by idiopathic overactive bladder or neurogenic bladder disorders (detrusor overactivity).
- Nocturnal enuresis associated with urinary urgency, in conjunction with medicine-free treatment when other treatments have been unsuccessful.

It contains 5 mg oxybutynin hydrochloride per tablet as the active substance, and it is given orally.

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

Important risks of Oxybutynin Macure, together with measures to minimise such risks and the proposed studies for learning more about Oxybutynin Macure'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, including PSUR assessment if applicable 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 Macure are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or taken. 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 Macure. 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.

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

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 Macure.

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

There are no studies required for Oxybutynin Macure.