Part VI: Summary of the risk management plan

Summary of risk management plan for Datolsigla (solifenacin succinate) 5mg and 10mg Film-coated Tablets

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

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

I. The medicine and what it is used for

Datolsigla is authorised for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome (see SmPC for the full indication). It contains solifenacin succinate as the active substance and it is given by oral route of administration.

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

Important risks of Datolsigla, together with measures to minimise such risks and the proposed studies for learning more about Datolsigla '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.

If important information that may affect the safe use of Datolsigla is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Datolsigla are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 Datolsigla. 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);

Summary of safety concerns	
Important identified risks	• Urinary retention • Prolongation of QT interval/ Torsade de points • Glaucoma • Ileus • Severe hypersensitivity reactions (angioedema, anaphylactic reaction)
Important potential risks	• None
Missing information	• Use of solifenacin in infants and children either exposed to solifenacin directly or exposed via breastfeeding. • Use in pregnancy

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

Not applicable