Summary of risk management plan for Mirabegron Glenmark 50 mg Prolonged-release tablet

This is a summary of the risk management plan (RMP) for Mirabegron Glenmark 50 mg Prolonged-release tablet. The RMP details important risks of Mirabegron Glenmark 50 mg Prolonged-release tablet, how these risks can be minimised, and how more information will be obtained about Mirabegron Glenmark 50 mg Prolonged-release tablet risks and uncertainties (missing information).

Mirabegron Glenmark 50 mg Prolonged-release tablet summary of product characteristics (SmPC) and its product information leaflet (PIL) give essential information to healthcare professionals and patients on how Mirabegron Glenmark 50 mg Prolonged-release tablet should be used.

I. The medicine and what it is used for

Mirabegron Glenmark 50 mg Prolonged-release tablet is authorised for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder syndrome.

It contains mirabegron as the active substance and it is given by oral route.

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

Important risks of Mirabegron Glenmark 50 mg Prolonged-release tablet, together with measures to minimise such risks and the proposed studies for learning more about Mirabegron Glenmark 50 mg Prolonged-release tablet 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 PIL 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 Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health Authority, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Mirabegron Glenmark 50 mg Prolonged-release tablet is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of Mirabegron Glenmark 50 mg Prolonged-release tablet 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 Mirabegron Glenmark 50 mg Prolonged-release tablet. 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 risk(s)	☐ None
Important potential risk(s)	• QT prolongation • Foetal disorders after exposure during pregnancy • Cardiac failure, particularly in patients with pre-existing cardiovascular diseases or cardiovascular risk factors
Missing information	☐ Paediatric use

II.B. Summary of important risk

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 Mirabegron Glenmark 50 mg Prolonged-release tablet.

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

There are no studies required for Mirabegron Glenmark 50 mg Prolonged-release tablet.