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Part VI: Summary of the risk management plan

Summary of risk management plan for Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur (Mirabegron)

This is a summary of the risk management plan (RMP) for Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur. The RMP details important risks of Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur, how these risks can be minimised, and how more information will be obtained about Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur's risks and uncertainties (missing information).

Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur should be used.

Important new concerns or changes to the current ones will be included in updates of Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur’s RMP.

I. The medicine and what it is used for

Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg

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forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur is authorised in the symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome (see SmPC for the full indication). It contains mirabegron as the active substance and it is given by oral administration.

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

Important risks of Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur, together with measures to minimise such risks and the proposed studies for learning more about Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur'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*.

If important information that may affect the safe use of Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg

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forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur 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 Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur. 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	• QT Prolongation • Fetal disorders after exposure during pregnancy • Cardiac failure, particularly in patients with with pre – existing cardiovascular diseases or cardiovascular risk factors
Missing information	• Pediatric use

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 Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur.

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

There are no studies required for Applicant's Mirabegron Zentiva/Aruverot/Mirabegron Aristo/Mirabegron Glenmark 50 mg forðatöflur/Mirabegron Adalvo 50 mg forðatöflur/Mirabegron Aristo Pharma/Alized 50 mg forðatöflur/Atinkers 50 mg forðatöflur/Mirabegron Heumann 50 mg forðatöflur/Preffin 50 mg forðatöflur/Mirabegron Avansor/MIRABEGRON/PHARMAZAC/Nicirch 50 mg forðatöflur/Kersion 50 mg forðatöflur.