Summary of risk management plan for AZISARTAN MEDOXOMIL (EDARBI)

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

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

This summary of the RMP for EDARBI should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of EDARBI's RMP.

I. The medicine and what it is used for

EDARBI is authorised for the treatment of essential hypertension in adults (see SmPC for the full indication). It contains AZILSARTAN MEDOXOMIL as the active substance and it is taken by ORAL ROUTE OF ADMINISTRATION.

Further information about the evaluation of EDARBI's benefits can be found in EDARBI EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/edarbi

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

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

II.A List of important risks and missing information

Important risks of EDARBI 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 EDARBI. 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	Foetotoxicity
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.

Important identified risk: Foetotoxicity	
Evidence for linking the risk to the medicine	Azilsartan medoxomil nonclinical and clinical studies. Case reports and reviews published in the medical literature of ARBs.
Risk factors and risk groups	Any exposure during pregnancy is deemed a risk.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.3, 4.4, 4.6, 5.3 and PL Additional risk minimisation measures: None
Additional pharmacovigilance activities	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 EDARBI.

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

There are no studies required for EDARBI.