

## Part VI: Summary of the Risk Management Plan

As the safety concerns and their management are identical for all products covered by this RMP, the information in Part VI is presented only once together for all products.

### Summary of risk management plan for Metformin Zentiva Filmtabletten (Metformin)

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

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

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

#### ***I. The medicine and what it is used for***

Metformin Zentiva Filmtabletten is authorised for the treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control (see SmPC for the full indication). It contains Metformin 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 Metformin Zentiva Filmtabletten, together with measures to minimise such risks and the proposed studies for learning more about Metformin Zentiva Filmtabletten'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.

#### **II.A List of important risks and missing information**

Important risks of Metformin Zentiva Filmtabletten 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 Metformin Zentiva Filmtabletten. 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).

<b>List of important risks and missing information</b>	
Important identified risks	Lactic acidosis (occurring with or without renal failure/impairment and/or concomitant use with iodinated contrast media)
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 Metformin Zentiva Filmtabletten.

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

There are no studies required for Metformin Zentiva Filmtabletten.